

UNITED STATES DISTRICT COURT

FOR THE

DISTRICT OF VERMONT

U.S. DISTRICT COURT
DISTRICT OF VERMONT
FILED

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A.F. OF L. – A.G.C. BUILDING TRADES)
WELFARE PLAN, individually and on behalf of)
itself and all others similarly situated,)
Plaintiff)

v.)

RECKITT BENCKISER, INC.; RECKITT)
BENCKISER, LLC; RECKITT BENCKISER)
HEALTHCARE (UK), LTD; RECKITT)
BENCKISER GROUP PLC, and RECKITT)
BENCKISER PHARMACEUTICALS, INC.)

Defendants)

Docket No. 1:13-cv-43

JURY TRIAL DEMANDED

CLASS ACTION COMPLAINT

Plaintiff A.F. of L. – A.G.C. BUILDING TRADES WELFARE PLAN, individually and on behalf of itself and all others similarly situated (“Plaintiff”) brings this class action against Reckitt Benckiser Group plc and Reckitt Benckiser Pharmaceuticals, Inc. (jointly “Reckitt” or “Defendants”). The following allegations are based on personal knowledge, the investigation of counsel and information and belief.

Nature of Action

1. This is a civil antitrust action seeking treble damages arising out of Reckitt’s unlawful exclusion of competition from the market for co-formulated buprenorphine hydrochloride and naloxone (“BPN/NLX”), a drug manufactured and sold by Reckitt under the brand-name Suboxone and used as maintenance treatment for people with opioid dependence.

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A PROFESSIONAL CORPORATION

2. Reckitt has sold branded Suboxone in two forms: orally dissolving tablets (“Suboxone Tablets”) and orally dissolving film strips (“Suboxone Film”).

3. Although all patent and/or regulatory exclusivity for Suboxone Tablets expired on October 8, 2009, generic versions of that drug have been and continue to be foreclosed from entering and effectively competing in the BPN/NLX market as a result of Reckitt’s “product hopping” scheme. As alleged more fully below, Reckitt engaged in various acts and practices as part of an overall scheme to switch the BPN/NLX market from Suboxone Tablets to Suboxone Film, a “new” patent-protected formulation of Suboxone that offers no additional benefit to consumers but has effectively prevented generic competition. As a result, Reckitt has been able to unlawfully maintain and extend its monopoly power in the market for BPN/NLX, to the detriment of Plaintiff and the Class (as defined below).

4. Defendant Reckitt Benckiser Pharmaceuticals, Inc. is a wholly-owned subsidiary of Defendant Reckitt Benckiser Group plc, a multinational conglomerate that manufactures and markets a variety of household, health and personal care, food, and pharmaceutical products worldwide. Net revenues for Reckitt Benckiser Group plc in 2011 exceeded \$14 billion. Its pharmaceutical division, the most profitable product of which is Suboxone, accounts for approximately 22% of total net revenues.

5. Many years ago, Reckitt developed two buprenorphine products for the treatment of opioid addiction: a single-entity buprenorphine product, Subutex, intended for brief induction stage, and Suboxone, a buprenorphine-naloxone combination drug for post-induction maintenance treatment. Reckitt began marketing Suboxone Tablets in 2002. Suboxone and Subutex were the only narcotic drugs available for the treatment of opioid dependence that could be prescribed in an office setting under the Drug Addiction Treatment Act (DATA) of 2000.

6. Prior to 2002, all approved opioid dependence treatments were required to be dispensed in clinics specializing in addiction treatment. Unlike Subutex, Suboxone is co-formulated with the opioid antagonist naloxone, which causes the immediate onset of withdrawal symptoms if the product is inappropriately melted and injected. With this abuse-deterrent property, Suboxone Tablets became popular in the U.S. for opioid dependence treatment outside of the clinical setting, and Reckitt quickly garnered substantial revenues from the sale of Suboxone Tablets – generating over \$800 million in U.S. sales from August 2010 to August 2011.

7. Regulatory orphan drug exclusivity for Suboxone Tablets expired on October 8, 2009. Reckitt knew that with no patent protection, generic manufacturers would seek FDA approval to sell lower-priced generic versions of Suboxone Tablets in direct competition by that date. Reckitt was also well aware that brand-name drugs typically lose 80% or more of their sales to less-expensive generic equivalents within the first year of competition and that it stood to lose hundreds of millions of dollars once generic Suboxone Tablets hit the market.

8. In response to the impending threat posed by generic competition, Reckitt implemented a multifaceted anticompetitive scheme, executed over the course of several years, to unlawfully maintain and extend its monopoly power in the BPN/NLX market by intentionally: (a) delaying market entry of less-expensive generic versions of Suboxone Tablets; and (b) preventing generic manufacturers from effectively and efficiently competing with branded Suboxone Tablets once they do enter the market in contravention of the intentions of Congress as embodied in the Drug Price Competition and Patent Term Restoration Act, Pub. L. No. 98-417, 98 Stat. 1585 (1984) (“Hatch-Waxman Act” or “Hatch-Waxman”).

9. Reckitt’s anticompetitive scheme included, among other things:

- a. Introducing a new Suboxone dosage form, Suboxone Film, which would not be substitutable by less-expensive generic versions of Suboxone Tablets at the pharmacy level. This new dosage formulation (as distinguished from the active ingredients in Suboxone and/or the use of those active ingredients to treat opioid dependency) is protected by a patent that does not expire until 2023, yet it offers no improved medical or clinical benefit to consumers over Suboxone Tablets as it contains the same active ingredients as Suboxone Tablets. Suboxone Film is not safer or more effective than Suboxone Tablets;
- b. Intentionally and unnecessarily disadvantaging Suboxone Tablets relative to Suboxone Film in the marketplace (and prior to market entry of generic Suboxone Tablets) by driving prescribers to switch prescriptions from Suboxone Tablets to Suboxone Film. Reckitt did this by: (A) not offering Suboxone Tablets in unit-dose packaging in the United States as it does with Suboxone Film, even though Reckitt offers the tablet product in unit-dose packaging in other countries and could have efficiently and effectively offered Suboxone Tablets in unit-dose packaging in the U.S.; (B) implementing a nationwide marketing campaign to malign the safety of Suboxone Tablets by focusing on the fact that Suboxone Tablets are not sold in unit-dose packaging (although they could be); (C) seeking an FDA determination that Reckitt's announced voluntary "discontinuation" of Suboxone Tablets – even though it still sells Suboxone Tablets in the U.S. – is for purported safety reasons due to the fact that they are not sold in

unit-dose packaging (a situation intentionally and unnecessarily created by Reckitt); and (D) unnecessarily increasing the price of Suboxone Tablets relative to Suboxone Film;

- c. Intentionally delaying the approval and launch of generic versions of Suboxone Tablets in order to create more time to shift market demand to the patent-protected film formulation by feigning cooperation with generic companies in the development of the Single Shared Risk Evaluation and Mitigation Strategy (“SSRS”) requested by the FDA in early 2012 in violation of 21 U.S.C. § 355- 1(f)(8); and
- d. Filing a fraudulent, sham “Citizen Petition” (“CP”) on the eve of generic approval, also for the purpose of artificially delaying the market entry of generic Suboxone Tablets (and, to the extent the CP is not a sham, intentionally delaying the filing of that CP to maximize delay of generic launch).

10. The scheme worked as planned. As a result of Reckitt’s anticompetitive scheme, less-expensive generic Suboxone Tablets remain unavailable in the United States, where the market for BPN/NLX has now been artificially converted almost entirely to the patent-protected Suboxone Film formulation.

11. But for Reckitt’s anticompetitive conduct, one or more less-expensive generic versions of Suboxone Tablets would have received final FDA approval and been launched in the U.S. market no later than the first half of 2012. Because of Reckitt’s predatory product conversion, failure to cooperate in the REMS process, and sham (and intentionally delayed) citizen petition, by the time generic manufacturers start selling their generic tablet versions of

Suboxone, the demand for Suboxone Tablets will have been almost entirely switched to Suboxone Film with the vast majority of prescriptions being written for that version. Because Suboxone Tablets constitute a different “dosage form” than Suboxone Film, pharmacists and others will be unable to automatically substitute less-expensive generic Suboxone Tablets for prescriptions written for Suboxone Film, even though the tablet and film products are clinically interchangeable and the film version offers patients no greater safety or efficacy than the tablets. Even though less-expensive generic equivalents typically capture well over 80% of the sales of its branded counterpart in its first year on the market, Reckitt’s scheme will cause the first manufacturers of generic Suboxone Tablets to come to market to capture only a small fraction of the BPN/NLX market and/or will discourage generic manufacturers from launching less-expensive competing generic versions of Suboxone altogether.

12. If Reckitt were simply and solely interested in introducing a new Suboxone Film product, which was supposedly superior to the existing tablet formulation, it could have done so without taking the additional, affirmative steps described herein to: (a) delay the market entry of less-expensive generic versions of Suboxone Tablets; and (b) interfere with the normal competition that routinely occurs between branded products and their generic counterparts as contemplated by the Hatch-Waxman Act. Moreover, and as covered in detail below, Reckitt’s purported safety concerns about its own tablet version (and corresponding claims of film superiority) are pretextual, as they either: (a) are completely contrived; or (b) to the extent not contrived, could have been efficiently and effectively cured by implementing unit-package dosing for the tablet product as Reckitt has done in other countries and as was feasible in the U.S.

13. Despite the generic manufacturers' efforts to seek and obtain FDA approval for generic versions of Suboxone Tablets, Reckitt maintains control of 100% of the BPN/NLX sales in the United States, generating over \$1 billion annually in revenues.Δ

14. As a result of its illegal scheme and abuse of the legitimate processes whereby generic drugs are expeditiously approved for the competitive benefit of U.S. purchasers, Reckitt: (a) illegally maintained and extended its monopoly in the market for BPN/NLX in the United States; (b) fixed, raised, maintained, and/or stabilized the price of BPN/NLX at supra-competitive levels; and (c) overcharged Plaintiff and other indirect purchasers of Reckitt's Suboxone Tablets by millions of dollars by depriving them of the benefits of competition from less-expensive generic versions of Suboxone Tablets.

15. Reckitt's monopoly power in the BPN/NLX market was maintained through willful exclusionary conduct, as distinguished from growth or development as a consequence of a legally-obtained valid patent, other legally-obtained market exclusivity, a superior product, business acumen, or historic accident.

Jurisdiction and Venue

16. This Court has jurisdiction over this action pursuant to 28 U.S.C. § 1332(d) because this is a class action in which the aggregate amount in controversy exceeds \$5,000,000 and at least one member of the putative class is a citizen of a state different from that of one of the defendants.

17. This Court also has jurisdiction over this matter pursuant to 15 U.S.C. § 26 and 28 U.S.C. §§ 1331 and 1337 in that Plaintiff brings claims under Section 16 of the Clayton Act, 15 U.S.C. § 26, for injunctive and equitable relief to remedy the Defendant's violations of Sections

1 and 2 of the Sherman Antitrust Act, 15 U.S.C. §§ 1 and 2. The Court has supplemental jurisdiction over Plaintiff's pendent state law claims pursuant to 28 U.S.C. § 1367.

18. Venue is appropriate within this district under Section 12 of the Clayton Act, 15 U.S.C. § 22 and 28 U.S.C. §1391(b) and (c), because Defendant transacts business within this district, and/or has an agent and/or can be found in this district, and the interstate trade and commerce, hereinafter described, is carried out, in substantial part, in this district.

Parties

19. Plaintiff A.F. of L. – A.G.C. Building Trades Welfare Plan (the “A.F.L. Plan”) is a self-insured health and welfare benefit plan with its principal place of business in Mobile, Alabama. The A.F.L. Plan provides reimbursement to its members for some or all of the purchase price of prescription drugs including Suboxone. The A.F.L. Plan represents participants who purchased and/or was provided reimbursement for some or all of the purchase price of Suboxone. The A.F.L. Plan paid more for than it would have for Suboxone absent Defendants' unlawful anticompetitive conduct to prevent generic entry and was injured as a result thereof.

20. Defendant Reckitt Benckiser Group plc is a British corporation incorporated under the laws of England and Wales, with its registered office located at 103 — 105 Bath Road, Slough, Berkshire, SL1 3UH. This defendant manufactures and markets numerous products, including pharmaceuticals subject to FDA approval, and was in whole or in part responsible for some or all of the conduct alleged above and below attributed to Reckitt.

21. Defendant Reckitt Benckiser Pharmaceuticals, Inc. is a Delaware corporation with its principal place of business located at 10710 Midlothian Turnpike, Suite 430, Richmond, Virginia 23235. This defendant manufactures and markets numerous products, including

pharmaceuticals subject to FDA approval, and was in whole or in part responsible for some or all of the conduct alleged above and below attributed to Reckitt.

22. Defendant Reckitt Benckiser Healthcare (UK) Ltd. is a British corporation incorporated under the laws of England and Wales, with its registered office located at Dansom Lane, Hull, North Humberside HU8 7DS. This defendant manufactures and markets numerous products, including pharmaceuticals subject to FDA approval, and was in whole or in part responsible for some or all of the conduct alleged above and below attributed to Reckitt.

23. Defendant Reckitt Benckiser, Inc. is a Delaware corporation with its principal place of business located at Morris Corporate Center IV, 399 Interpace Parkway, Parsippany, New Jersey 07054. This defendant manufactures and markets numerous products, including pharmaceuticals subject to FDA approval, and was in whole or in part responsible for some or all of the conduct alleged above and below and attributed to Reckitt.

24. Defendant Reckitt Benckiser LLC is a Delaware limited liability company with its principal place of business located at Morris Corporate Center IV, 399 Interpace Parkway, Parsippany, New Jersey 07054. This defendant manufactures and markets numerous products, including pharmaceuticals subject to FDA approval, and was in whole or in part responsible for some or all of the conduct alleged above and below and attributed to Reckitt.

25. All of Reckitt's actions described in this complaint are part of, and in furtherance of, the illegal monopolization and attempted monopolization alleged herein, and were authorized, ordered, and/or done by Reckitt's various officers, agents, employees, or other representatives while actively engaged in the management of Reckitt's affairs (or that of their predecessors-in-interest) within the course and scope of their duties and employment, and/or with the actual, apparent, and/or ostensible authority of Reckitt.

I. CLASS ACTION ALLEGATIONS.

26. Plaintiff brings this action on behalf of itself and, under Rules 23(a),(b)(2) and (b)(3) of the Federal Rules of Civil Procedure, as representative of a Class defined as follows:

All persons or entities in the United States and its territories who purchased and/or paid for some or all of the purchase price of Suboxone in any form, for consumption by themselves, their families, or their members, employees, insureds, participants, or beneficiaries, other than for resale, at any time during the period January 1, 2012, through the present and continuing until the anticompetitive effects of Defendants' unlawful conduct cease (the "Class"). For purposes of the Class definition, persons or entities "purchased" Suboxone if they paid or reimbursed some or all of the purchase price.

The following persons or entities are excluded from the proposed indirect purchaser class:

- a. Defendants and their respective subsidiaries and affiliates;
- b. All governmental entities (except for government funded employee benefit plans);
- c. All persons or entities who purchased Suboxone for purposes of resale or directly from a Defendant to the extent and solely to the extent of such purpose for resale or as a direct purchase;
- d. Insured individuals covered by plans imposing a flat dollar co-pay that was the same dollar amount for generic as for brand drug purchases;
- e. Fully insured health plans, *i.e.* plans that purchased insurance from another third-party payor covering 100% of the plan's reimbursement obligations to its members;
- f. All judges presiding in this case and all counsel or record

27. Members of the Class are so numerous that joinder is impracticable. Plaintiff believes the Class numbers in the hundreds. Further, the Class is readily identifiable from information and records in the possession of Reckitt.

28. Plaintiff's claims are typical of the claims of the members of the Class. Plaintiff and all members of the Class were damaged by the same wrongful conduct by Reckitt, *i.e.*, they paid artificially inflated prices for BPN/NLX and were deprived of the benefits of competition

from less-expensive generic versions of Suboxone Tablets as a result of Reckitt's wrongful conduct.

29. Plaintiff will fairly and adequately protect and represent the interests of the Class. Plaintiff's interests are coincident with, and not antagonistic to, those of the Class.

30. Plaintiff is represented by counsel who are experienced and competent in the prosecution of class action antitrust litigation, and have particular experience with class action antitrust litigation in the pharmaceutical industry.

31. Questions of law and fact common to the members of the Class predominate over questions, if any, that may affect only individual Class members because Reckitt has acted on grounds generally applicable to the entire Class. Such generally applicable conduct is inherent in Reckitt's wrongful conduct.

32. Questions of law and fact common to the Class include:

- a. whether Reckitt unlawfully maintained monopoly power through its overarching scheme;
- b. whether Reckitt unlawfully maintained monopoly power through its product hopping strategy;
- c. whether Reckitt unlawfully maintained monopoly power through its wrongful manipulation of the SSRS process;
- d. whether Reckitt unlawfully maintained monopoly power through its improper filing of a sham and/or fraudulently delayed citizen petition;
- e. whether the challenged activities of Reckitt suppressed generic competition to Suboxone;
- f. whether Reckitt's challenged conduct harmed competition in the market(s) in which Suboxone is sold;
- g. whether direct proof of Reckitt's monopoly power is available, and if available, whether it is sufficient to prove Reckitt's monopoly power without the need to also define a relevant market;

- h. to the extent a relevant market or markets must be defined, what that definition is or those definitions are;
- i. whether the activities of Reckitt as alleged herein have substantially affected interstate commerce;
- j. whether, and to what extent, Reckitt's conduct caused antitrust injury to the business or property of Plaintiff and the members of the Class, and;
- k. the quantum of damages paid by the Class in the aggregate.

33. Class action treatment is a superior method for the fair and efficient adjudication of the controversy in that, among other things, such treatment will permit a large number of similarly situated persons to prosecute their common claims in a single forum simultaneously, efficiently, and without the unnecessary duplication of evidence, effort, and expense that numerous individual actions would engender. The benefits of proceeding through the class mechanism, including providing injured persons or entities with a method for obtaining redress on claims that might not be practicable to pursue individually, substantially outweigh any difficulties that may arise in management of this class action.

34. Plaintiff knows of no difficulty to be encountered in the maintenance of this action that would preclude its maintenance as a class action.

II. FACTUAL ALLEGATIONS.

A. The Regulatory Structure Pursuant To Which Brand And Generic Drugs Are Approved.

1. The Hatch-Waxman Framework.

35. Under the Federal Food, Drug and Cosmetics Act (21 U.S.C. §§ 301-392) ("FDC Act"), a manufacturer who creates a new drug must obtain the approval of the Food and Drug Administration ("FDA") to sell the new drug by filing a New Drug Application ("NDA"). An NDA must include submission of specific data concerning the safety and efficacy of the drug, as well as any information on applicable patents.

36. In 1984, Congress amended the FDC Act with the enactment of the Drug Price Competition and Patent Term Restoration Act, Pub. L. No. 98-417, 98 Stat. 1585 (1984), commonly referred to as the Hatch-Waxman Act.

37. Hatch-Waxman simplified the regulatory hurdles for prospective generic manufacturers by eliminating the need for them to duplicate the clinical studies used to obtain approval for the brand-name counterpart drug. Instead, based on well-established scientific principles, the FDA provides an expedited scientific review process by which generic manufacturers may file and gain approval for their drugs through the filing of an Abbreviated New Drug Application (“ANDA”).

38. The ANDA relies on the scientific findings of safety and efficacy included by the brand-name drug manufacturer in the original NDA. The ANDA filer, however, must scientifically demonstrate to the FDA that the generic drug it is going to market is just as safe and just as effective as the corresponding brand-name drug through demonstrations of bioequivalence. A demonstration of bioequivalence means that, within certain set parameters of variability, the generic product delivers the same amount of active ingredient into the patient’s blood stream for the same amount of time as does the corresponding brand drug. The range of acceptable variability afforded to generic drugs for demonstrating bioequivalence is the same lot-to-lot (i.e., batch-to-batch) range of variability afforded to brand companies when manufacturing their own brand drug.

39. Generally speaking, ANDA filers that demonstrate bioequivalence are seeking to have their generic products deemed to be “AB-rated” to the corresponding brand-name drug, sometimes referred to as the “reference listed drug.” AB-rated generics are those that have been determined by the FDA to be therapeutically equivalent (i.e., bioequivalent) and

pharmaceutically equivalent to their brand-name counterparts. Pharmaceutical equivalence means the generic drug and branded reference listed drug have, among other things, the same active ingredient, same strength, same route of administration, and same dosage form. Generic drugs that do not fulfill all of these requirements cannot be deemed to be AB-rated to the targeted reference listed drug.

40. Hatch-Waxman also provides brand-name manufacturers with several means, in addition to traditional patent rights, to obtain legitimate protection from generic competition for set, and specifically limited, periods of time. For example, each approved NDA provides the owner of that drug three (3) years of exclusivity. *See* 21 U.S.C. § 355(j)(5)(F)(iii). For pioneer drugs that are truly new or innovative in that they make use of a never-before-approved chemical entity or moiety – as opposed to an NDA relating to the far more common reformulations or dosage changes for existing drugs – the FDA grants a “New Chemical Entity” (“NCE”) exclusivity period of five (5) years. *See* 21 U.S.C. § 355(j)(5)(F)(ii). Outside of the Hatch-Waxman context, if an NDA drug treats a rare condition, the FDA may grant an additional seven (7) years of Orphan Drug exclusivity during which time no corresponding ANDA drug may be approved or commercialized.

2. AB-rated Generic Versions Of Brand-Name Drugs Are Significantly Less Expensive, And Take Significant Sales Directly From The Corresponding Brand-Name Versions.

41. Competition from lower-priced AB-rated generic drugs saves American consumers billions of dollars a year. As set forth *infra*, however, these consumer savings mean lower profits for brand drug companies. It is well-established that when AB-rated generic entry occurs, the brand drug company suffers a rapid and steep decline in sales and profits on its reference listed drug.

42. The threat of AB-rated generic competition thus creates a powerful incentive for brand companies to protect their revenue streams. This incentive can prompt brand companies to create innovative new products or new versions of old products that offer real medical benefits to patients. It may also drive brand companies to seek to obstruct generic drug competition by making changes to existing products that offer patients little or, as here, no therapeutic advantages whatsoever, but are intended to interfere with the normal brand-to-generic competition contemplated and encouraged by the Hatch-Waxman Act and various state laws.

43. Such tactics, often referred to as “product switching” or “product hopping,” can be an effective, albeit anticompetitive, way to game the regulatory structure that governs the approval and sale of generic drugs, thereby frustrating the efforts of federal and state law designed to promote and facilitate price competition in pharmaceutical markets. As discussed in detail below, a brand company can interfere with the mechanism by which generic drugs compete by making non-therapeutic changes to its branded product, and can effectively prevent generic competition, not because the reformulated product is an improvement over the original version of the product or is preferred by consumers, but simply because it differs in strength, route of administration, or, as here, dosage form.

44. Typically, AB-rated generic versions of brand-name drugs are priced significantly below their brand-name counterparts. Because of the price differentials and other institutional features of the pharmaceutical market, AB-rated generic versions are rapidly and substantially substituted for their more expensive brand-name counterparts. When multiple generic manufacturers enter the market, prices for generic versions of a drug predictably decrease even more significantly because of competition among the generic manufacturers, and the loss of sales volume by the brand-name drug to the corresponding generics is dramatic.

45. An AB rating is particularly significant to a generic manufacturer because, under Hatch-Waxman and most state Drug Product Selection laws (“DPS laws”), pharmacists may (and, in many states, must) substitute an AB-rated generic version of a drug for the brand-name drug without seeking or obtaining permission from the prescribing doctor (unless the prescription is denominated “Dispense as Written,” or “DAW”). Indeed, both Congress and state legislatures have actively encouraged generic substitution because of their recognition that the economics of the pharmaceutical industry prevent generic manufacturers from simultaneously: (a) engaging in the type of heavy promotion or “detailing” typically done by brand-name manufacturers; and (b) providing the enormous cost savings to purchasers and consumers generated by generic drugs.

46. AB-rated generic competition enables indirect purchasers to: (a) purchase generic versions of brand-name drugs at substantially lower prices; and/or (b) purchase the brand-name drug at reduced prices. However, until generic manufacturers enter the market with an AB-rated generic, there is no bioequivalent generic drug which competes with the brand-name drug and therefore, the brand-name manufacturer can continue to charge supra-competitive prices profitably without losing all or a substantial portion of its brand-name sales.

47. This statutorily mandated process, however, is anticompetitively manipulated when brand-name manufacturers, like Reckitt here, introduce a new version of an already-existing drug that is no safer and no more effective than the original version, and switch the market to the “new” version thereby causing the conversion of prescriptions for the original drug to be written for the “new” version. The result is that, by the time generic versions of the original brand drug reach the market, there are few, if any, prescriptions being written for the original brand version and, because there is some slight difference between the generic drug and the “new” brand drug (e.g., different milligram strength, route of administration, or dosage form),

automatic substitution of the less-expensive generic for the more-expensive brand prescriptions cannot take place. This leaves the generic manufacturer with a couple of choices, both of which result in significantly higher prices for purchasers: (a) implement its own extensive sales and marketing campaign for its generic drug, which dramatically increases the price for its product (and, as a practical matter, acts as a barrier to meaningful market entry); or (b) abandon altogether its generic product, meaning no generics are available. This anticompetitive result is only exacerbated when the brand company takes additional steps to delay the market entry of generics while it implements the switch scheme, as Reckitt did here.

B. Background And Approval Of Suboxone.

48. Opioid addiction and abuse is a pervasive public health problem that plagues patients, families, and communities.¹ In 2010, the Substance Abuse and Mental Health Services Administration (“SAMHSA”) reported in the National Survey on Drug Use and Health that over 1.9 million Americans suffer from opioid dependence or abuse.²

49. Prior to 2002, patients who suffered from opioid addiction were primarily referred to a narcotic treatment program (“NTP”) for opioid maintenance treatment using methadone. Methadone is a Schedule II controlled substance³ and a full mu-opioid receptor agonist similar to

¹ Reckitt Citizen Petition (“Reckitt CP” or “CP”) (attached hereto as Exhibit A), (9/25/2012) FDA-2012-P-1028 at 6, *citing*, Guide to Drug Abuse Epidemiology, Department of Mental Health and Substance Dependence, Noncommunicable Diseases and Mental Health Cluster, World Health Organization (2000), available at <http://whglbdoc.vhoint/hq/2000/a58352 PartA.pdf>.

² *Id.* at 7, *citing* Buprenorphine. Center for Substance Abuse Treatment, Substance Abuse and Mental Health Services Administration, Results from the 2010 National Survey on Drug Use and Health: Summary of National Findings, NSDUH Series H-41, HHS Publication No. (SMA) 11-4658, available at <http://www.samhsa.gov/data/NSDUH/2k1ONSDUH/2k1OResults.htm>.

³ *Id.*, *citing* 21 U.S.C. § 812(c) (2010). The U.S. Drug Enforcement Administration (“DEA”) places drugs and other substances in a respective schedule according to their relative abuse potential and accepted medical use. For example, Schedule I controlled substances have no currently accepted medical use and a high potential for abuse, and Schedule II controlled substances have a currently accepted medical use but a higher potential for abuse than Schedule III, IV, or V controlled substances. *Id.* at (b).

other highly abused opiates such as heroin.⁴ To mitigate the risk of diversion (i.e., use for recreational purposes) associated with prescribing methadone to opioid addicted patients, methadone may only be administered to treat addiction in a facility specifically registered by the U.S. Drug Enforcement Administration as a NTP.⁵

50. Many opioid dependent patients avoided NTPs due to privacy concerns and the perceived stigma attached to those programs, rendering methadone an incomplete answer to the demand for opioid addiction treatment.⁶ Accordingly, in 2000, Congress sought to improve access to opioid addiction treatment via the Drug Addiction Treatment Act (“DATA”).⁷ DATA enabled practitioners who obtained special training to administer Schedule III, IV, or V controlled substances to a certain number of patients in an office-based setting.⁸

51. Reckitt developed two (2) buprenorphine products for the treatment of opioid addiction: a single-entity buprenorphine product, Subutex, intended for a brief induction stage, and Suboxone, a buprenorphine-naloxone combination drug for post-induction maintenance treatment.⁹ Prior to these drugs being approved in 2002 by the FDA, buprenorphine was rescheduled from Schedule V to Schedule III and they (Subutex Tablets and Suboxone Tablets) became the first opioid addiction treatments available outside an NTP pursuant to DATA 2000.¹⁰

⁴ *Id.*, citing About Buprenorphine Therapy, U.S. Dep’t of Health and Human Services, <http://buprenorphine.samhsa.gov/about.html>.

⁵ *Id.*, citing 21 C.F.R. § 1306.07 (2012).

⁶ *Id.* at 7, citing Elisa F. Cascade et al., *Prescribing for Buprenorphine in the Treatment of Opioid Addiction*, 4(1) *Psychiatry* 15, 15-16 (2007).

⁷ *Id.*

⁸ *Id.* at 7-8, citing Drug Addiction Treatment Act of 2000, Pub. L. No. 106-310, § 3502, 114 Stat. 1222-7 (2000).

⁹ *Id.* at 8.

¹⁰ *Id.* at 8.

52. Although Suboxone was approved by the FDA in 2002, it had no patent protection and instead relied primarily on seven (7) years of orphan drug exclusivity. The FDA designated Suboxone Tablets as an orphan drug for the treatment of opioid addiction on October 27, 1994. Orphan drug designation and approval may be granted: (1) on the basis that a product is intended to treat a disease or condition that has a U.S. prevalence of less than 200,000 persons (FDC Act § 526(a)(2)(A)); or (2) where the sponsor can show that there is no reasonable expectation that the costs of developing and making available the drug will be recovered from U.S. sales, despite the fact that the product treats a disease or condition that has a U.S. prevalence of 200,000 or more individuals (FDC Act § 526(a)(2)(B)). Here, Reckitt put forth arguments for orphan designation based on both FDC Act § 526(a)(2)(A) (prevalence) and § 526(a)(2)(B) (cost recovery). Although the FDA did not agree with Reckitt's prevalence figures, the Agency concluded that the economic analysis and supporting documentation submitted by Reckitt were sufficient to support a cost recovery designation. Suboxone's orphan drug exclusivity expired October 8, 2009.

53. Suboxone quickly became a billion-dollar-a-year product for Reckitt despite the representation in its successful application for orphan drug exclusivity that there was no reasonable expectation that Reckitt could recover the costs associated with making and developing the drug.

1. The Product Switch: Hopping From Tablets To Film.

54. With the limited exclusivity of Suboxone Tablets in mind, Reckitt began implementing a strategy to maintain its BPN/NLX monopoly by commencing development of a patent-protected Suboxone Film product. Reckitt submitted the Suboxone Film NDA to the FDA on October 20, 2008, and it was approved in September 2010. The three (3) year regulatory exclusivity for Suboxone Film extends to August 2013, and patent number 8,017,150 entitled

“Polyethylene Oxide-Based Films and Drug Delivery Systems Made Therefrom,” which Reckitt listed in the FDA’s Orange Book for Suboxone Film, will not expire until September 2023. Because Suboxone Film does not make use of a never-before-used active ingredient it did not, and does not, qualify for the five (5) year New Chemical Entity Exclusivity.

55. Suboxone Film product in and of itself offers no additional medical or clinical benefits to consumers over Suboxone Tablets because it contains the same active ingredients as the tablet version and is clinically interchangeable with the tablets. It is no safer and no more effective than Suboxone Tablets. To the contrary, Suboxone Film product raises new safety concerns in the context of accidental pediatric exposures that are not associated with Suboxone Tablets: “[T]he more rapid dissolution of this dosage form compared to the tablets, and the difficulty of spitting it out once it is placed in the mouth, could actually contribute to more severe outcomes when the product is accidentally taken by a small child.” *See* Amneal Pharmaceuticals, LLC’s October 22, 2012 Comment and Request for Summary Denial of Petition (“Amneal Comment”) (attached hereto as Exhibit B), Docket No. FDA-2012-P-1028, at 11, quoting FDA Cross-Discipline Team Leader Review, NDA 22-410 (Suboxone Film) (October 20, 2010). Nevertheless, Suboxone Film offered huge financial benefits to Reckitt because unlike the tablets, it is patent protected until 2023 and there are no pending ANDAs seeking approval to market generic versions of the film formulation.¹¹

¹¹ The barriers to entry by a generic drug manufacturer are high. Such companies must first formulate a non-infringing generic version of the brand name drug; conduct bioequivalence studies and other studies needed to support the ANDA; file the ANDA and work with FDA on any issues that arise regarding approval; either challenge relevant patents or wait for them to expire; wait for expiration of any applicable regulatory exclusivities; and invest in manufacturing facilities for the commercialization of the product. It is not economically rational for generic manufacturers to engage in these costly activities until regulatory and patent exclusivity expirations near. This is all the more so when generic companies have already heavily invested in formulating and pursuing FDA approval of a generic version of a brand name drug only to have the brand name manufacturer make a therapeutically meaningless formulation change

56. Reckitt purposefully developed its “new” version of Suboxone with a different dosage form than the pre-existing tablets so that generic tablets, when approved, would not be AB-rated to (and therefore not automatically substitutable for) the Suboxone Film.

57. Immediately upon FDA approval of the Suboxone Film in 2010, Reckitt implemented massive sales and marketing strategies to convert all BPN/NLX prescriptions from Suboxone Tablets to Suboxone Film. These strategies included, among other things: (a) instructing sales representatives to promote only the film formulation and discourage physicians from writing prescriptions for the original tablet formulation under the pretext of alleged safety concerns; (b) announcing that it was pulling Suboxone Tablets from the market due to the purported but pretextual safety issues; and (c) seeking an FDA determination that Suboxone Tablets were being voluntarily pulled from the market by Reckitt due to the contrived safety issues.

58. To further drive the conversion to the new film product prior to the launch of the AB-rated generic tablet product, Reckitt also raised the price of the tablets in relation to the film formulation and instituted programs that provided co-pay discounts/rebates to consumers who purchased the film formulation.

59. Reckitt’s 2011 Annual Report explains the product hopping strategy and its goal of thwarting effective generic competition in the Suboxone franchise:

and switch the market to that new formulation for the anticompetitive purpose of thwarting meaningful competition from the existing generic product. This puts the generic manufacturer in the position of having to: (1) engage in prohibitively expensive marketing of its generic drug, which would dramatically increase the price of its product as specifically not contemplated and intended by the Hatch-Waxman Act and state substitution laws; or (2) scrap its investment in the initial generic version of the drug and re-invest in developing a second generic product equivalent to the next version of the branded counterpart drug, all in the hopes that additional switches will not take place prior to approval and launch of the second generation generic product. *See, generally, Abbott Laboratories v. Teva Pharmaceuticals USA, Inc.*, 432 F.Supp.2d 408 (D. Del. 2006).

“As a result of the loss of [Suboxone Tablet] exclusivity in the US, up to 80% of the revenue and profit of the Suboxone tablet business in the US might be lost in the year following the launch of generic competitors, with the possibility of further erosion thereafter. However, in the event of generic competition to the Suboxone tablet, the Group expects that the Suboxone sublingual film will help to mitigate the impact...The patent-protected Suboxone film continued to grow, and by the end of December had captured a 48% volume share of the total market and has further strengthened its position as market leader, ahead of tablets.” 2011 Annual Report at 11 (available at <http://www.rb.com/Investors-media/Investor-information>, last accessed January 27, 2013).

60. Reckitt’s product hopping strategy has been overwhelmingly successful, as the film formulation accounted for over 70% of current Suboxone prescriptions by mid-2012. *See* <http://seekingalpha.com/article/889861-reckitt-s-decision-opens-the-door-for-titan-pharma-and-biodelivery-sciences> (last accessed January 27, 2013).

61. In addition, Reckitt knew that this strategy would successfully prevent generic entry into the Suboxone market because they used an identical “product-switching” strategy in the United Kingdom with respect to their heartburn drug Gaviscon. When Gaviscon’s patent expired in 1999, Reckitt used the rationale of “health and safety” to institute a product switch which led to a finding of anticompetitive behavior by the United Kingdom’s Office of Fair Trading and a fine in excess of 10.2 million pounds. *See* Julia Kollewe, *Reckitt Benckiser fined £10.2m by OFT: Drug company stopped NHS doctors prescribing cheaper alternatives to its heartburn medicine Gaviscon*, The Guardian, Oct. 15, 2010 available at <http://www.guardian.co.uk/business/2010/oct/15/reckitt-benckiser-fined-of-gaviscon> (last accessed February 25, 2013).

62. Further, on September 25, 2012, Reckitt announced the discontinuation of the branded Suboxone Tablets in the U.S. market. As with the conversion of the Suboxone market from tablet to film, Reckitt’s discontinuation of its branded Suboxone Tablets has an anticompetitive purpose and a profound anticompetitive effect. Through this tactic, Reckitt

assures that by the time the generic tablets enter the marketplace, there will be few, if any, prescriptions being written for Suboxone Tablets and virtually nothing for which the less-expensive generic tablets can be substituted.

63. Upon information and belief, while Reckitt has announced its intention to withdraw Suboxone Tablets from the market due to an alleged safety issue, it is still selling some amount of this product while it continues to convert the market fully from tablets to film. This continued sale of tablet product highlights that Reckitt's alleged safety concerns regarding the tablet version are not legitimate, but simply part of its anticompetitive switch strategy.

64. Reckitt's justification for its continued tablet sale is simply a pretext to hide its true anticompetitive motives. On the one hand, Reckitt argues to the FDA that would-be generic competitor "Amneal seems unconcerned about the devastating effect on patients and the treatment community that would be caused by a precipitous removal, and ignores the mandatory 6-month notice period required under section 506C of the FDC Act." Reckitt's Supplemental Response ("Reckitt Response") (attached hereto as Exhibit C), (11/16/2012) Docket No. FDA-2012-P1028 at 4 n. 5. On the other hand, Reckitt's self-serving argument is at odds with their own behavior: (a) the applicable statutory provision Reckitt quotes, 21 U.S.C. 356c, allows for the reduction of the 6-month period in instances where "a public health problem may result from continuation of the manufacturing for the 6-month period" and upon information and belief, Reckitt has not sought FDA permission to shorten this period due to purported safety concerns; (b) Reckitt has been selling the allegedly safety-superior film version for over two years, thus there would be no precipitous absence of Suboxone on the market; and (c) Suboxone Tablets are not currently listed on FDA's public list of drugs to be discontinued, suggesting that Reckitt has

not actually provided formal notice of discontinuation to FDA as mandated by 506C of the FDA Act (and also suggesting that Reckitt's public announcement of discontinuation is simply a ruse).

65. On information and belief, Reckitt incurred significant additional expense in researching and developing Suboxone Film and developing commercial manufacturing processes for this product. Reckitt has also incurred significant additional expense in seeking FDA approval for the branded film version. It has also cost Reckitt substantial amounts to "detail" doctors and market the film formulation to health care entities with the goal of switching prescriptions and prescribing habits from the tablet product to the clinically interchangeable film products. However the "new" film product is priced lower than the original tablet formulation.

66. Reckitt cannot justify the incurrence of these costs and its associated product-hopping conduct by claiming a desire to introduce a supposedly "better" or "superior" product because the Suboxone Film is clinically interchangeable and provides no material benefits to consumers that the tablets did not already provide and/or could have easily provided with very slight, cost effective modification to the packaging of the tablet version. And, as alleged above, Suboxone Film raises certain safety concerns that are unique to it and not present in Suboxone Tablets.

67. Reckitt's pricing of Suboxone Film confirms that this formulation provides no medical benefits over Suboxone Tablets. In the two-year period beginning with the launch of the film formulation in 2010, Reckitt increased the price of the tablets in relation to the film. Had the reformulation increased the value to consumers of the film as compared to the tablets, Reckitt, as a rational profit-maximizing company, would have captured part of that value in its pricing. It did not attempt to capture any added value through increased pricing of the film, but instead: (a) raised the price of the tablets in relation to the film solely to convert the BPN/NLX market from

the tablet form to the film form; and (b) took actions to delay entry of generic forms of Suboxone Tablets that would be priced less than branded Suboxone Tablets and Film.

68. Moreover, even if the film had some benefit over the tablets (which it does not), such benefit could have been offered without: (a) delaying the market entry of generic versions of Suboxone Tablets; or (b) eliminating or discouraging demand for Suboxone Tablets by unnecessarily disadvantaging the tablet product. Additionally, the alleged benefit of the film version could have been implemented with the U.S. tablet version. Reckitt touts the increased safety of Suboxone Film over Suboxone Tablets resulting from the fact that the film version is packaged in individual unit doses to prevent unintended exposure to children, but the tablet version is not. This is also the safety basis for which Reckitt claims to be discontinuing sales of the tablet version in the U.S. But Reckitt could have made that same unit-dose packaging change to Suboxone Tablets sold in the U.S. as it has done for the Suboxone Tablet product marketed in other countries, and as Reckitt itself said was feasible for tablet product sold in the U.S. (*See* Reckitt CP at 22, n. 57, Exhibit A).

69. Had Reckitt not acted to destroy the demand for Suboxone Tablets and delay the entry of less-expensive generic versions of Suboxone Tablets, doctors and patients would have more readily been able to weigh the relative medical benefits and prices of tablets versus film, and choose the formulation they preferred. Since Reckitt's true goal was to interfere with and impede generic competition to the greatest extent possible and for the longest time possible, it took steps to intentionally disadvantage Suboxone Tablets that had enjoyed overwhelming market success for a decade and took affirmative steps to delay market entry of less-expensive generic versions of Suboxone Tablets, all in order to deny purchasers the ability to choose the formulation they prefer.

2. Tactics To Delay Generic ANDA Approval.

70. While fully engaged in efforts to extend its monopoly by converting the BPN/NLX market from tablets to film and destroying the existing market for the BPN/NLX tablets, Reckitt also pursued a campaign to indefinitely delay the approval of all generic BPN/NLX tablet ANDAs.

71. Reckitt was aware of pediatric exposure issues regarding Suboxone as early as 2002. (See Reckitt Response at 2, Exhibit C). Indeed, Reckitt sells Suboxone Tablets in blister packaging in Canada and Europe. See, e.g., Canadian Suboxone Monograph at 22, *available at* <http://freepdfhosting.com/d721c1d74a.pdf> (last accessed January 27, 2013).

72. Rather than making a simple packaging change to unit-dose packaging in the U.S. years ago for Suboxone Tablets, Reckitt recognized that it could use the packaging issue to delay and impede the successful launch of generic competitors to its multi-billion dollar Suboxone Tablet franchise in the U.S. by: (a) blister-packing an alternative dosage formulation (Suboxone Film) while not blister-packing Suboxone Tablets; then (b) waiting until the last possible moment to raise safety issues with the FDA relating to the tablet packaging, which ANDA filers were required to mimic. Reckitt did just that.

73. Under the Food and Drug Administration Amendments Act of 2007, the FDA has the authority to require Risk Evaluation and Mitigation Strategies (“REMS”) from manufacturers to ensure that the benefits of a drug or biological product outweigh its risks. REMS can include a medication guide, a package insert and potential restrictions on the distribution of the drug (e.g., by requiring practitioners, pharmacies or healthcare settings to obtain special certifications in order to dispense the drug).

74. In enacting the REMS framework, Congress anticipated that brand-name drug manufacturers like Reckitt would attempt to use REMS programs as a basis for impeding generic

competition. Accordingly, Congress enacted Section 505-1(f)(8) of the FDC Act (21 U.S.C. § 355-1(f)(8) which prohibits a brand-name drug manufacturer from using REMS “to block or delay approval of an” ANDA.

75. On December 22, 2011, having considered and evaluated Reckitt’s data on reported pediatric exposures associated with Suboxone Tablets, the FDA approved Reckitt’s proposed REMS for branded Suboxone Tablets. The agency addressed the pediatric exposure issue in the REMS, requiring that Reckitt address pediatric exposures associated with Suboxone Tablets through FDA-approved labeling (*See* Amneal Comment at 3, Exhibit B). The FDA did not require that the pediatric exposure issues be addressed outside the realm of the FDA-approved product labeling and REMS.

76. On January 6, 2012, two weeks after approval of the Suboxone Tablet REMS, the FDA sent all sponsors of pending ANDAs for Suboxone Tablets, including Amneal Pharmaceuticals, LLC (“Amneal”), a REMS Notification Letter explaining that all branded and generic BPN/NLX products would be subject to a Single Shared REMS program (SSRS). *Id.* at 3.

77. The Notification Letter advised the generic ANDA filers to contact Reckitt to collaborate on the creation and implementation of an SSRS program. *Id.* The Notification Letter also stated that pediatric exposure would be addressed in the REMS. *Id.* The FDA mandated a compliance date of May 6, 2012, for approved products, by which time it expected that the SSRS with Reckitt would be accomplished. *Id.*

78. The FDA reasonably expected that the approved Suboxone REMS could be amended to add generic manufacturers in a relatively short time. *Id.* Indeed, there would have been no reason for the FDA to withhold approval for REMS for generic Suboxone that were identical in all material respects to the REMS it had approved one month earlier for the branded

Suboxone. In order to make that submission, however, the generics needed access to Reckitt's information regarding the recently approved Suboxone REMS.

79. Because the SSRS was a precondition to the approval of Amneal's and other generics' Suboxone Tablet ANDAs, Amneal and other generic ANDA filers promptly notified Reckitt of the FDA's Notification Letter and requirement. *Id.* at 4.

80. Reckitt thereby confirmed that Amneal and other generic companies had pending ANDAs. *Id.* Reckitt took advantage of its access to this proprietary information by feigning cooperation in the SSRS development process and diligently working to delay the ANDA approvals. *Id.*

81. During the next six months, Amneal and the other ANDA applicants for generic versions of Suboxone Tablets (along with ANDA holders for the single ingredient buprenorphine-containing products) sought to negotiate the SSRS with Reckitt in good faith and with due urgency to secure prompt approvals of its products. *Id.* Reckitt, however, used every opportunity to delay the process, making unnecessary, unprecedented, and unreasonable demands on the generic companies as a precondition to Reckitt's cooperation in the development of the SSRS, *id.*, all in violation of 21 U.S.C. § 355-1(f)(8) of the FDA Act.

82. Specifically, as stated by Amneal to the FDA:

[Reckitt] initially informed the generic companies that it would wait until it received confirmation from FDA of the requirement for a SSRS before working on it. While waiting for a response from [Reckitt], the ANDA sponsors joined together as a group in early February 2012 to form a Buprenorphine Products Manufacturers Group (BPMG), and submitted formal correspondence to [Reckitt] on February 8, 2012, regarding a request for collaboration on a SSRS. On February 14, 2012, [Reckitt] informed the BPMG that it had received the communication from FDA, but that, due to purported antitrust issues, its legal department would handle future communications regarding the SSRS. While waiting for a response from [Reckitt's] legal representative, the generic members of the BPMG initiated weekly meetings beginning on February 23, 2012.

[Reckitt] turned down numerous invitations to participate in the meetings. On March 20, 2012, [Reckitt's] legal representative provided the BPMG with a list of legal and governance issues that it demanded be resolved before [Reckitt] would engage in any substantive discussions involving an SSRS. In particular, [Reckitt's] "gating issues" involved: (1) a mission statement describing the BPMG's commitment to patient safety; (2) an upfront agreement on cost-sharing for REMS implementation and activities; and (3) an upfront agreement that all manufacturers would share the costs of product liability for future potential lawsuits. These demands made clear that [Reckitt] was seeking to leverage access to its REMS program to its own commercial advantage. [Reckitt] finally agreed to meet with the BPMG in person on April 2, 2012. But at the meeting, [Reckitt] refused to engage in any substantive discussions about the REMS and would only provide legal staff to attend the meetings until the "gating issues" were resolved to [Reckitt's] satisfaction. Consistent with past experience and to expedite the process, the generic companies sought to develop the REMS in parallel with the discussions and negotiation of legal issues. [Reckitt] undermined the effort by refusing this approach while also refusing to share non-public information, documentation, or any description of its REMS program – despite having entered into a confidentiality agreement with the BPMG – until its gating issues were resolved. Although the gating issues had nothing to do with the content or administration of an SSRS, in a good faith effort at cooperation, the generic members of the BPMG worked on the issues for weeks with [Reckitt]. Ultimately, the BPMG members could not commit to a binding agreement on cost sharing until they reviewed the costs associated with [Reckitt's] program (which [Reckitt] refused to provide) and could not agree to [Reckitt's] unprecedented demand on product liability sharing as a required precursor to SSRS discussions.

Id at 4, n. 3.

83. While ostensibly negotiating the SSRS, Reckitt at the same time retained the services of RADARS and the Venebio Group to prepare a study to explore the risk of pediatric exposure to Suboxone Tablets. *Id.* at 4.

84. In May 2012, after months of futile discussions with Reckitt regarding an SSRS, during which period Reckitt refused to share any non-public information about its existing REMS program, Amneal and the other generic tablet ANDA applicants jointly requested a meeting with the FDA to discuss the delays created by Reckitt. *Id.* The FDA scheduled the meeting for June 18, 2012, and invited Reckitt. *Id.*

85. After reviewing the written materials submitted by Reckitt and the BPMG, and hearing each party's oral presentations, the FDA agreed at the meeting with Amneal and the other generic ANDA filers that, as a result of Reckitt's refusal to cooperate and share information about its REMS and the FDA's inability to compel Reckitt to share the information, the only viable alternative would be for the generic companies and Reckitt to develop a new SSRS based upon the requirements set forth in the REMS Notification Letter, without utilizing any of Reckitt's existing information (which Reckitt refused to provide). *Id.* at 4-5. Reckitt advised the FDA at the meeting that it would cooperate with the generic sponsors to develop this new SSRS, which Reckitt knew was necessary for generic sponsors to obtain approval of its respective ANDAs. *Id.* at 5.

86. Through Reckitt's participation in that process, Reckitt obtained proprietary information regarding the filing status, timing, and content of the proposed new SSRS. *Id.* Despite its commitment to cooperate, Reckitt's intransigence and delay tactics continued. *Id.* For instance, Reckitt refused to sign a governing Memorandum of Understanding for the group unless it was given veto authority or a super-majority vote for all issues relating to the administration of the SSRS. *Id.* at 5, n. 5. It continued its demand that each BPMG member agree to share a pre-specified percentage of all product liability claims, regardless of fault, despite the fact that no other shared REMS program has adopted this approach. *Id.* The FDA-negotiated Extended Release Long Acting Opioid SSRS does not have any provision dealing with the issue of sharing product liability claims, and other SSRS programs have standard cross-indemnification provisions for fault-based claims. *Id.* Yet Reckitt insisted on unprecedented commercial obligations on the generic members of the BPMG for future product liability claims. *Id.* Indeed, as certain generic members of the BPMG explained to Reckitt, the upfront agreement

being sought by Reckitt would deprive these companies of coverage under its product liability insurance policies. *Id.*

87. In mid-August 2012, Amneal, together with other generic ANDA applicants, filed the SSRS with the FDA as part of their respective applications. Despite its active involvement in the development of the SSRS, Reckitt refused to submit the new SSRS with its NDA filing. As Amneal specifically alleged in its recent filing with the FDA:

Two days before the scheduled submission of the REMS documents to FDA in mid-August, [Reckitt] suddenly raised an issue regarding a prescriber outreach component of the SSRS involving the use of a field force, arguing that an important element of the REMS had been omitted. The ANDA sponsors were astonished that [Reckitt] raised this matter only a few hours before finalization of the REMS documents. The ANDA sponsors had no objection to exploring this option, but believed that it should be tabled until the group received comments from the FDA's review of the REMS documents about to be submitted.

Id. at 5, n.6.

88. In mid-September 2012, the FDA provided comments regarding the proposed new SSRS. *Id.* at 5. Within two weeks, Amneal and the other generic sponsors jointly responded to the FDA comments. *Id.* Despite Reckitt's refusal to file the SSRS as part of its NDA, Reckitt maintained that it desired to continue collaborating on the SSRS development. *Id.* Such continued involvement allowed Reckitt to maintain its awareness of the status of the SSRS and to use such information to the detriment of the generic tablet ANDA filers as described below.

Id. at 5.

89. On October 3, 2012, as a result of Reckitt's refusal to cooperate in good faith in the development of the SSRS, Amneal and the other generic tablet ANDA filers elected to file a Waiver Request with the FDA, seeking the approval of a generics-only SSRS. *Id.*

3. Reckitt Files A Fraudulent And Baseless Citizen Petition.

90. Under Section 505(j) of the FDC Act a person may file what is called a “citizen petition” with the FDA requesting, among other things, that the agency take, or refrain from taking, any form of administrative action to address genuine concerns about the safety, scientific, or legal issues regarding a product anytime before, or after, its market entry. The citizen petition process has been historically misused by some brand-name pharmaceutical manufacturers as a tactic to extend their monopolies on certain brand-name drugs.¹² These citizen petitions are often filed on the eve of FDA approval of an ANDA for competing AR-rated generic drugs. Final approval of a pending ANDA is typically delayed for several months, but may be delayed for over a year, while the FDA evaluates the citizen petition (even those that are meritless, due simply to the time it takes the review and process the material, including responses thereto).

91. On September 25, 2012, just prior to the submission of the REMS Waiver Request by the generic ANDA sponsors, Reckitt announced its intent to permanently withdraw Suboxone Tablets from the U.S. market for reasons of safety and filed a citizen petition with the FDA to block approval of all pending Suboxone ANDAs on alleged safety grounds (Exhibit A). *See also* Amneal Comment at 6, Exhibit C). Reckitt’s petition argues that, after 10 years on the market, Reckitt has suddenly discovered a safety issue so severe as to require the removal of Suboxone Tablets, just as the generic REMS process (which was already wrongfully delayed by Reckitt) was coming to its expected close and the pending generic tablet ANDAs were ripe for approval. Amneal Comment at 6, Exhibit B.

¹² *See* Comment of the Staff of the Bureau of Competition and of Policy Planning of the Federal Trade Commission, at <http://www.ftc.gov/bc/v0000005.pdf>, last accessed January 27, 2013.

92. Reckitt's citizen petition raising purported safety issues with generic versions of Suboxone Tablets is a meritless sham filed solely to delay generic entry, and to artificially protect and extend its Suboxone monopoly. To the extent the citizen petition has any merit (which it does not), Reckitt fraudulently delayed raising such issues with FDA for the sole purpose of maximizing the delay of the approval of less-expensive generic versions of Suboxone Tablets.

93. In its citizen petition, Reckitt requests three actions from the FDA:

- a. That the FDA refrain from approving any buprenorphine NDA or ANDA for the treatment of opioid addiction that does not include a targeted pediatric exposure education program because those applications are not approvable pursuant to sections 505(b) and (j) of the FDC Act, despite the fact that the educational programs raised by Reckitt are not required by the FDA for branded Suboxone Tablets and pediatric exposure issues are already dealt with in the FDA-approved REMS and labeling for branded Suboxone.
- b. That the FDA refrain from approving applications for buprenorphine for opioid addiction that lack child-resistant unit-dose packaging, despite the fact that Reckitt has known about the risk of accidental pediatric exposure for over ten years, has sold and continues to sell Suboxone Tablets in non-unit-dose containers for over ten years in the U.S., and could have easily employed unit-dose packaging for its U.S. tablet product long ago (as it has for tablet products sold in other countries).

- c. That the FDA not approve any buprenorphine/naloxone ANDA for addiction treatment until the FDA determines whether the reference listed drug, Suboxone Tablets, was discontinued for safety reasons, despite the fact that Reckitt still sells Suboxone Tablets in the U.S., and the reason for the alleged safety defect (i.e., lack of unit-dose packaging) is a matter of Reckitt's own intentional creation.
- a. The Citizen Petition Is Baseless Since The FDA Has No Statutory Or Regulatory Authority To Grant The Types Of Relief Sought By Reckitt.

94. Reckitt requests that the FDA “refrain from approving any buprenorphine NDA or ANDA for the treatment of opioid addiction that does not include a targeted pediatric exposure education program because those applications are not approvable pursuant to sections 505(b) and (j) of the FDC Act.” Reckitt CP at 6, Exhibit A. This request is baseless since the FDA has no statutory or regulatory authority to grant this relief.

95. Reckitt's request that the FDA require unit-dose packaging to prevent unintentional pediatric exposures is within the exclusive jurisdiction of the Consumer Product Safety Commission (“CPSC”) rather than the FDA. Thus, the FDA cannot grant the relief requested. *See* Amneal Comment at 13-16, Exhibit B.

96. Further, Reckitt is well aware that it's “targeted pediatric exposure education program” is not part of the FDA-approved REMS or labeling for Suboxone Tablets. The FDA has no statutory or regulatory ability to require ANDA filers to mimic non-approved labeling and REMS materials in order to obtain approval. Reckitt can obtain this relief only by petitioning Congress to alter the statutory provisions that state the specific requirements that ANDAs must meet in order to obtain approval.

97. More specifically, the FDA-approved Suboxone labeling and REMS provided to patients, pharmacists, and prescribers cautions about keeping the product out of the reach of children. Reckitt's proposed educational program was not incorporated by Reckitt into its own REMS program and has not been approved or otherwise required by the FDA as part of its formally approved labeling or REMS. As relevant to this issue, Section 505(j)(4)(G) of the FDC Act and 21 C.F.R. § 314.127(a)(7) require that ANDA filers mimic "the labeling approved for the listed drug referred to in the [ANDA]." In submitting ANDAs, applicants are required to provide a copy of the proposed label and labeling for the product. 21 C.F.R. § 314.94(a)(8)(ii). The regulations make clear that the "[l]abeling (including the container label, package insert, and, if applicable, Medication Guide) proposed for the drug product must be the same as the labeling approved for the [reference listed brand drug]," with limited enumerated exceptions not applicable here. 21 C.F.R. § 314.94(a)(8)(iv). The approved labeling for the reference listed brand drug is publicly available on the Drugs@FDA website, which is the primary source for identifying and locating the labeling that must be mimicked by ANDA filers. *See* <http://www.accessdata.fda.gov/scripts/cder/drugsatfda/> (last accessed January 27, 2013).

Regarding Suboxone Tablets, the Drugs@FDA website includes the currently-approved labeling, REMS, and medication guide distributed by Reckitt, but contains no references to or information about the "education program" that Reckitt improperly asks the FDA to require of ANDA filers.

98. Had Reckitt desired to have such educational programs be part of its formally approved labeling and REMS – and hence, make them mandatory for ANDA filers – it could have filed a supplement to its NDA for Suboxone Tablets with the FDA seeking such approval. But, to date, it has not done so. As a result, these educational programs are not required of

ANDA filers and Reckitt's citizen petition asking the FDA to mandate that these programs be instituted by ANDA filers as part of their approval process is baseless.

99. Similarly, Reckitt's request that the FDA not approve ANDAs for generic versions of Suboxone Tablets that do not contain the educational materials referenced above, since "such ANDAs allegedly would "lack the same risk-benefit profile" as Suboxone Tablets, is objectively baseless in that: (a) there is no statutory or regulatory support for such a "risk-benefit sameness" evaluation of ANDAs; and (h) incorporation of such a standard would require that the FDA either change or violate the Hatch-Waxman Act, which it does not have the power to do.

b. Reckitt's Request That FDA Not Approve Any ANDAs Until FDA Determines Whether Suboxone Tablets Were Withdrawn for Safety Reasons Is Baseless.

100. Reckitt's citizen petition also asks that the FDA not approve any ANDAs for generic versions of Suboxone Tablets until the FDA determines whether or not Suboxone Tablets were withdrawn from the market for safety reasons. Reckitt CP at p. 6, Exhibit A. In support of this request, Reckitt argues that it "concluded that the balance of risk to benefit, in light of readily available safer alternatives (Suboxone Film) justified the discontinuance." *Id.* at 43. This request is baseless as is the factual premise underlying it.

101. Although Reckitt argues in the citizen petition as though it has actually discontinued the sale of Suboxone Tablets, it in fact continues to sell the product. At a minimum, this request is not ripe for adjudication by the FDA. Neither the FDC Act nor FDA regulations permit the FDA to engage in advisory opinions about the reasons why a drug has been discontinued when in fact it has not been discontinued. Further, the Suboxone Tablet product is not included on the FDA's list of drugs to be discontinued, which suggests that Reckitt has not formally advised the FDA of its alleged discontinuance or intent to discontinue.

102. To the extent Reckitt has actually discontinued selling Suboxone Tablets, its request is still baseless since: (a) Reckitt has sold Suboxone Tablets in non-unit-dose packaging for over ten years, despite its knowledge of the risks of accidental pediatric exposures; (b) Suboxone Tablets sold in bulk containers are and have been safe and effective when used as directed; (c) Suboxone Tablets have FDA-approved labeling and REMS in place to assist in avoiding accidental pediatric exposures; and (d) there is no statutory or regulatory support for the proposition that one approved drug can be declared to be “unsafe” based on relative safety comparisons to a wholly different approved drug product.

103. In addition, Reckitt’s inconsistent conduct belies its meritless claim on this point. Instead of actually discontinuing the sale of Suboxone Tablets, Reckitt has also stated its intention to continue the sale of its self-proclaimed “unsafe” tablet product for six months from the date of filing the citizen petition. Not coincidentally, the six-month window that Reckitt allows for the discontinuation of its tablet product corresponds precisely to the 180 days allowed for FDA action on the citizen petition, which is now the last impediment to generic ANDA approval. Reckitt, obviously, desires to maximize profits by selling both Suboxone Tablets and Film during this period of time. Also, Reckitt’s alleged justification for continuing with the sale of its alleged “unsafe” Suboxone Tablets is meritless window-dressing. Reckitt has attempted to justify this continued tablet sale by arguing to the FDA that would-be generic competitor “Amneal seems unconcerned about the devastating effect on patients and the treatment community that would be caused by a precipitous removal, and ignores the mandatory six (6) month notice period required under section 506C of the FDC Act.” Reckitt Response, at 4 n. 5, Exhibit C. Reckitt’s excuse, however, is a pretext to hide its true anticompetitive motives since: (a) the applicable statutory provision, 21 U.S.C. 356c, allows for the reduction of the six (6)

month period in instances where “a public health problem may result from continuation of the manufacturing for the 6-month period”; (b) Reckitt has been selling the allegedly safer superior film version for over two years; and (c) it does not appear that Reckitt has formally advised FDA of its actual or intended discontinuance of Suboxone Tablets as required, and thus has not even invoked the application of 506C.

c. Reckitt’s Alleged New-Found Safety Issues Are Baseless.

104. Reckitt argues in the citizen petition that FDA should refrain from approving ANDAs for generic versions of Suboxone Tablets that lack unit-dose packaging. Reckitt CP at 38. Reckitt argues that it has demonstrated a safety issue regarding Suboxone Tablets based on various graphic presentations of data regarding pediatric exposures of products identified as buprenorphine, Suboxone Tablets, and Suboxone Film, and an abstract of a study conducted by the Venebio Group.

105. Reckitt’s alleged safety issues and the specific relief requested are baseless. First and foremost, Reckitt’s arguments are disingenuous in that Reckitt still sells Suboxone Tablets in bulk packaging in the U.S. If Reckitt truly believed that selling Suboxone Tablets in bulk packaging was unsafe, it would have either: (a) already discontinued the sale of this product, instead of simply feigning to do so for posturing purposes; or (b) changed over to unit-dose packaging for its tablet product, as it sells in other countries and admits was feasible for tablets sold in the U.S.

106. Also, the citizen petition on this point is facially inadequate because it fails to include any of the data and analyses upon which it relies. In Section 505(q) petitions that could delay approvals of pending applications, the petitioner is required to certify, *inter alia*, that the petition “includes all information and views upon which the petition relies.” FDC Act § 505(q)(1)(H).

107. Although Reckitt provided this certification, Reckitt CP at 48, it failed to include any data, case notes, or actual analyses upon which it relies. Reckitt's failure to comply with Section 505(q) and with its own certification denies the ANDA applicants who are targeted by the petition an opportunity to comment on the core data and analyses that Reckitt proposes should delay or preclude approval of those applications.

108. Reckitt's data and analyses are based ultimately on spontaneous reports of pediatric exposures which cannot, in and of themselves, demonstrate the nature, incidence, or cause of a reported event or the level of injury associated with the event, particularly for the types of reporting-rate comparisons in Reckitt's petition.

109. Moreover, in its review of the Suboxone Film NDA, the FDA refused to accept Reckitt's assertion that unit-dose packaging for the film product would ensure greater safety against accidental pediatric exposures. *See* Amneal Comment at 11 *citing* Cross-Discipline Team Leader Review, NDA 22-410, at 4 (October 20, 2010), Exhibit B. ("[T]he more rapid dissolution of this dosage form compared to the tablets, and the difficulty of spitting it out once it is placed in the mouth, could actually contribute to more severe outcomes when the product is accidentally taken by a small child."). The summaries of data and analyses in the citizen petition do not address severity of injuries associated with reported pediatric exposures. *Id.* at 11-12.

d. The Citizen Petition Includes A False And Fraudulent Certification Regarding Its Timeliness; Reckitt Fraudulently Delayed Raising Safety Issues.

110. Based on a comparison of the respective package inserts, it appears that Reckitt manufactures and packages Suboxone Tablets for the U.S. in the same manufacturing site in Hull, U.K. that is utilized for manufacture of the unit-dose blister packaged tablet product sold by Reckitt in the U.K.. and elsewhere. *Id.* at 8 n. 13.

111. To the extent legitimate, Reckitt's request that the FDA require unit-dose blister packaging to prevent pediatric exposure could have been raised years ago to the proper agency and could have been directly addressed by Reckitt by providing Suboxone Tablets in the same or similar unit-dose packaging that it sells in the UK and elsewhere. *See, e.g., Canadian Suboxone Monograph at 22* available at <http://freepdfhosting.com/d721c1d74a.pdf> (*last accessed January 27, 2013*). Instead, Reckitt continued to sell billions of dollars worth of bulk containers of tablets in the U.S. without concern, only to proffer a last-minute demand that its competitors should be precluded from the market because of the absence of such packaging. Reckitt did not raise the unit-dose blister packaging issue to prevent pediatric exposure years ago because Reckitt desired to delay generics and buy time to switch the Suboxone Tablet market to the film formulation and diminish the tablet market to a point where it would be uneconomical for some or all generics to even launch an equivalent BPN/NLX tablet product or even pursue approval for generic versions of the film formulation. *See footnote 11 supra.*

112. Reckitt elected to mute its concerns while transitioning patients to film and feigning engagement in the development of the SSRS, all in an effort to further delay generic entry. Then, on what Reckitt knew to be the eve of generic entry in September 2012 (despite the above-described efforts to delay generic approval via the SSRS process), it filed the citizen petition, making the knowingly false certification to the FDA that the information on which Reckitt based its citizen petition first became known to Reckitt on or about September 15, 2012. *See Reckitt CP at 48, Exhibit A.* Indeed, Reckitt's CP itself reveals the fraudulent nature of this representation. The CP goes on at length to describe the history of accidental pediatric exposure to Suboxone and Reckitt's knowledge about that issue over a long period of time. Just a few of the concessions in the CP are as follows: "as addressed in Subutex's and Suboxone's labeling,

the effects of exposure are particularly acute in young children and can be severe” (*Id.* at p. 10); “A report based on data from AAPCC showed 53 exposures to buprenorphine in children under six in 2004” (*id.* at 18); “By 2006, the number reported by AAPCC had jumped to 204 exposures among children under the age of six” (*id.*); “By June of 2007, [Reckitt] had developed materials for an education campaign to inform patients and providers of the unique risks of pediatric exposure to buprenorphine.” (*id.* at 19); “...in March 2008, [Reckitt] amended its labeling for Suboxone to include a warning that patients should ‘always store buprenorphine-containing medications safely and out of the reach of children...’” (*id.*); “This was not the first time that [Reckitt] recognized the value of unit-dose packing of buprenorphine. [Reckitt] had been working to develop unit-dose packaging for Suboxone tablets since before the product was first approved for marketing....Although later studies revealed unit-dose packaging of Suboxone may be feasible, [Reckitt] focused its resources on the development of Suboxone Film” (*id.* at 22, n. 57).

113. Reckitt’s concerns in the citizen petition over pediatric exposure and the need for unit-dose packaging are transparently disingenuous and were fraudulently delayed for anticompetitive purposes. Rather than work with generic companies on the SSRS to address pediatric exposures, Reckitt sought to transform such exposures into a competitive advantage by: (a) not changing the packaging of its tablet product years ago; (b) encouraging physicians to switch patients from Suboxone Tablets to the patent-protected and blister-packed Suboxone Film, although the film version in and of itself does not constitute a safer or more effective product; and (c) manipulating the ANDA approval process to forestall or prevent altogether the marketing of generic tablets, allowing Reckitt to more thoroughly convert the market from the branded tablets to the branded film.

C. Effects On Competition And Damages To Plaintiff and Class.

114. The purpose and effect of Reckitt's strategy was to foreclose (and/or severely limit) generic competition that otherwise would have existed through sales of Suboxone Tablets. By engaging in this scheme, Reckitt did not simply delay sales of generic Suboxone Tablets; it took additional steps that had the purpose and effect of impeding those generic tablets from ever meaningfully competing with Suboxone products, even once generic competitors are legally permitted to begin sales, by destroying any demand for Suboxone Tablets before generics can enter the market.

115. Had generics been able to start selling their less-expensive versions of Suboxone Tablets before Reckitt implemented the switch to films, the generic manufacturers would have successfully entered the BPN/NLX market and would have captured significant sales. This is because, if a generic BPN/NLX formulation had been available and on the market before Reckitt implemented the switch to films, there would have been continuing pressure from the managed care industry for patients to continue to be prescribed Suboxone Tablets. Since generic products will not get to market before the switch is completed, the managed care industry will not be able to exert pressure to return patients to the generic Suboxone Tablets once those products become available since they are not AR-rated to Suboxone Film. By taking actions that have postponed the launch date for generic Suboxone Tablets, Reckitt barred generic competitors from the market entirely, again effectively preserving the BPN/NLX market solely for the benefit of Reckitt's monopoly profits.

116. Reckitt's exclusionary conduct has delayed, prevented, and impeded the sale of generic BPN/NLX in the United States, and unlawfully enabled Reckitt to sell Suboxone at artificially inflated prices. But for Reckitt's illegal conduct, generic competitors would have been able to successfully market generic versions of Suboxone tablets by the first half of 2012, if not

earlier. Reckitt's scheme to change product formulations and discontinue the already existing product, while simultaneously delaying generic entry, as alleged above, is exclusionary and unreasonably restrains competition.

117. To the extent that Reckitt has any valid business purpose for its conduct, that purpose could be served by means that are less restrictive of competition, and would at all events be outweighed by the anticompetitive effects of the conduct. Among other things, Reckitt could have launched a new film product without taking affirmative steps to destroy the demand for the existing tablet product. Reckitt could have also blister-packed its U.S. Suboxone Tablet product many years ago, just as they sell Suboxone Tablets in Canada and Europe and admit was feasible for tablets sold in the U.S. Reckitt's conduct has allowed, and continues to allow, it to maintain a monopoly and exclude competition in the relevant market, to the detriment of all BPN/NLX purchasers, including Plaintiff, members of the Class, and consumers. Accordingly, the anticompetitive effects of Reckitt's conduct clearly outweigh the purported procompetitive benefits (if any) of such conduct.

118. Similarly, Reckitt cannot justify its conduct with any supposed consumer benefit, as the enormous cost savings offered by generic drugs outweigh any supposed benefit from the film formulation of Suboxone, which benefits are illusory and/or could have been obtained without taking affirmative steps to destroy demand for Suboxone Tablets. Reckitt's exclusionary motive is also illustrated by its willingness to sacrifice profits as part of the market switch strategy: Reckitt's decision to incur the extra costs necessary to change formulations was economically rational only if the change has the effect of excluding generic competition for Suboxone Tablets. But for the impact on generic competition, Reckitt would not have invested the resources necessary to bring the Suboxone Film to the market. But for the impact on generic

competition, it would not have been economically rational to invest in the process of developing the clinically interchangeable film formulation, seeking FDA approval of that formulation, changing the manufacturing process, and engaging in significant marketing efforts to switch the market from tablets to film.

119. Had Reckitt not intentionally delayed generic ANDA approval by feigning cooperation in SSRS development and filing the sham citizen petition, multiple generic BPN/NLX products would have been approved and launched by the first half of 2012, if not earlier. Additionally, had Reckitt filed the citizen petition when it first became aware of the alleged safety benefits of unit-dose packaging, rather than filing on the eve of generic approval and fraudulently certifying that the petition was based on information that first became known to Reckitt on or about September 15, 2012, any issues presented in the citizen petition would have been resolved many years ago, and multiple generic BPN/NLX products would have been approved and launched by the first half of 2012 at the latest.

120. Alternatively, even assuming that the citizen petition had objective merit and its filing was not fraudulently delayed, had Reckitt not delayed the generics by feigning cooperation in SSRS development, multiple generic ANDAs would have been approved and the generic products would have launched prior to the September 2012 filing date of the citizen petition. The previously-approved generic products would not have been removed from the market as a result of the filing of the citizen petition as evidenced by the fact that Reckitt's tablet product continues to be sold in the market while its petition remains pending.

121. If manufacturers of generic Suboxone Tablets had been able to enter the marketplace earlier, as set forth above, Plaintiff and other members of the Class would have substituted lower-priced generic Suboxone Tablets for the higher-priced brand-name Suboxone

Tablets for some or all of their requirements, and/or would have paid lower prices for some or all of their remaining Suboxone Tablet purchases.

122. During the relevant period, Plaintiff and other members of the Class purchased substantial amounts of Suboxone Tablets and/or Film directly from Reckitt. As a result of Reckitt's illegal conduct alleged herein, Plaintiff and other members of the Class were compelled to pay, and did pay, artificially inflated prices for their Suboxone requirements. Plaintiff and the other Class members paid prices for Suboxone that were substantially greater than the prices that they would have paid absent the illegal conduct alleged herein, because: (a) class members were deprived of the opportunity to purchase lower-priced generic Suboxone Tablets instead of expensive brand-name Suboxone; and (b) the price of branded Suboxone was artificially inflated by Reckitt's illegal conduct. As a consequence, Plaintiff and other members of the Class have sustained substantial losses and damage to their business and property in the form of overcharges.

D. Effects On Interstate And Intrastate Commerce.

123. At all material times, Suboxone, manufactured and sold by Reckitt, was shipped across state and national lines and sold to customers located outside its state of manufacture throughout the United States and within each of the States therein.

124. During the relevant time period, in connection with the purchase and sale of Suboxone, monies as well as contracts, bills and other forms of business communication and transactions were transmitted in a continuous and uninterrupted flow across state and national lines.

125. During the relevant time period, various devices were used to effectuate the illegal acts alleged herein, including the United States mail, interstate and foreign travel, and interstate and foreign telephone commerce. The activities of Reckitt, as charged in this

Complaint, were within the flow of, and have substantially affected interstate commerce and intrastate commerce. Reckitt's anticompetitive conduct has substantial intrastate effects in that, *inter alia*, retailers within each state are foreclosed from offering cheaper generic Suboxone to end-payors inside each respective state. The complete foreclosure of generic Suboxone from the market directly impacts and disrupts commerce for end-payors within each state.

E. Monopoly Power.

126. Through the anticompetitive conduct alleged herein, Reckitt has been able to charge supra-competitive prices for BPN/NLX and enjoys abnormally high price-cost margins on its sales of BPN/NLX products, and thus, by definition, maintains market power and/or monopoly power with respect to BPN/NLX sold in the United States.

127. To the extent that Plaintiff is required to prove monopoly power circumstantially by first defining a relevant product market, Plaintiff alleges that the relevant product market is all BPN/NLX products – i.e., Suboxone in all its forms and dosage strengths.

128. Because Suboxone is the only narcotic drug that is available for the treatment of opioid dependence and that: (a) can be prescribed in an office setting under the Drug Addiction Treatment Act (DATA) of 2000; and (b) is co-formulated with an opioid antagonist to deter abuse, there are no reasonably interchangeable drug products that are available to prescribing physicians for the maintenance treatment of opioid dependence outside of the clinic setting. For the entire period relevant to this case, Reckitt has been able to profitably maintain the price of its branded BPN/NLX products well above competitive levels.

129. A small but significant, non-transitory price increase for BPN/NLX products by Reckitt would not have caused a significant loss of sales.

130. Suboxone does not exhibit significant, positive cross-elasticity of demand with respect to price with any product other than AB-rated generic versions of Suboxone.

131. The relevant geographic market is the United States and its territories.

132. At all relevant times, Reckitt enjoyed high barriers to entry with respect to the above-defined relevant market due to patent and other regulatory protections, and high costs of entry and expansion.

133. Reckitt have had, and exercised, the power to exclude and restrict competition to Suboxone.

134. Reckitt's market share in the relevant market is and was 100% at all times.

135. Reckitt's actions are part of, and in furtherance of, the illegal monopolization alleged herein, were authorized, ordered or done by Reckitt's officers, agents, employees or representatives while actively engaged in the management of Reckitt's affairs.

136. Reckitt's illegal acts to prevent the introduction and/or dissemination into the U.S. marketplace of any generic version of Suboxone resulted in Plaintiff and the Class paying more than they would have paid for BPN/NLX, absent Reckitt's illegal conduct.

III. CAUSES OF ACTION.

COUNT I

Monopolization: Unlawful Maintenance Of Monopoly Power Through An Overarching Scheme To Prevent Or Delay Generic Competition

137. Plaintiff refers to, and incorporates herein, the allegations above in ¶¶ 1-136.

138. At all relevant times, Reckitt possessed monopoly power in the relevant market.

139. Reckitt manufactured the various formulations of Suboxone described herein.

Reckitt, *inter alia*, marketed and sold those various versions of Suboxone in the United States.

During the relevant period, Reckitt willfully and unlawfully maintained its monopoly power by engaging in exclusionary conduct that discouraged rather than encouraged competition on the

merits. As explained in detail above, Reckitt engaged in an exclusionary scheme that included, *inter alia*, each of the following (at various times):

- a. converting the market from Suboxone Tablets to Suboxone Film, which is no safer or more effective than Suboxone Tablets;
- b. intentionally refusing to unit-dose pack Suboxone Tablets for the purpose of creating the illusion that Suboxone Film is a superior product;
- c. raising the price of Suboxone Tablets in relation to Suboxone Film;
- d. directing Reckitt's detailers to market only Suboxone Film and to urge physicians not to write prescriptions for Suboxone Tablets;
- e. stating an intent to withdraw Suboxone Tablets from the market,
- f. feigning cooperation with the generics and intentionally delaying the creation of a unified or generics-only REMS for Suboxone Tablets;
- g. filing a sham citizen petition with the FDA for the sole purpose of maximizing the delay of generic ANDA approvals; and
- h. intentionally and fraudulently delaying the filing of the citizen petition in order to maximize the period of delay of generic ANDA approvals.

140. The goal, purpose and/or effect of Reckitt's scheme was to prevent, delay, and/or minimize the success of the entry of generic competitors which would have sold generic Suboxone Tablets in the United States at prices significantly below Reckitt's prices for Suboxone, which would have effectively caused the average market price of Suboxone to decline dramatically.

141. The goal, purpose and/or effect of Reckitt's scheme was also to maintain and extend Reckitt's monopoly power with respect to BPN/NLX. Reckitt's illegal scheme to exclude, delay, and/or minimize the success of the introduction into the United States marketplace of any generic versions of Suboxone Tablets enabled Reckitt to continue charging supra-competitive prices for BPN/NLX without a substantial loss of sales.

142. As a result of Reckitt's illegal scheme, Plaintiff and members of the End-Payor Class more than they would have paid for BPN/NLX, absent Reckitt's illegal conduct. But for Reckitt's illegal conduct, competitors would have begun marketing generic versions of Suboxone well before they actually did, and/or would have been able to market such versions more successfully upon entry than they actually did.

143. If manufacturers of generic BPN/NLX had been able to enter the market and compete with Reckitt in a full and timely fashion, Plaintiff and members of the End-Payor Class would have substituted lower-priced generic BPN/NLX for some or all of their BPN/NLX requirements, and/or would have received lower prices on some or all of their remaining branded Suboxone purchases.

144. During the relevant period, Plaintiff and the members of the End-Payor Class purchased substantial amounts of Suboxone directly from Reckitt. As a result of Reckitt's illegal conduct alleged herein, Plaintiff and the other members of the End-Payor Class were compelled to pay, and did pay, artificially inflated prices for their BPN/NLX requirements. Plaintiff and members of the End-Payor Class paid prices for BPN/NLX that were substantially greater than the prices that they would have paid absent the illegal conduct alleged herein, because: (a) class members were deprived of the opportunity to purchase lower-priced generic BPN/NLX instead of expensive brand-name Suboxone; and/or (b) the price of branded Suboxone was artificially inflated by Reckitt's illegal conduct.

145. The injury to the Plaintiff and the members of the End-Payor Class is the type of injury state antitrust laws are designed to prevent, and the injury was a direct and proximate result of Defendant Reckitt's unlawful conduct.

146. Reckitt's scheme was in the aggregate an act of monopolization undertaken with the specific intent to monopolize the market for BPN/NLX in the United States.

147. Plaintiff and the End-Payor Class seek damages and multiple damages as permitted by law for their injuries by Reckitt's violations of the following state antitrust laws:

- a. Defendants have intentionally and wrongfully engaged in monopolization in the relevant market in violation of Arizona Rev. Stat. §§ 44- 1402, *et seq.*, with respect to purchases of Suboxone in Arizona by members of the Class.
- b. Defendants have intentionally and wrongfully engaged in monopolization in the relevant market in violation of Cal. Bus. & Prof. Code §§ 16700, *et seq.*, with respect to purchases of Suboxone in California by members of the Class.
- c. Defendants have intentionally and wrongfully engaged in monopolization in the relevant market in violation of D.C. Code §§ 28-4503, *et seq.*, with respect to purchases of Suboxone in the District of Columbia by members of the Class.
- d. Defendants have intentionally and wrongfully engaged in monopolization in the relevant market in violation of Fla. Stat. §§ 501.201, *et seq.*, with respect to purchases of Suboxone in Florida by members of the Class.
- e. Defendants have intentionally and wrongfully engaged in monopolization in the relevant market in violation of Hawaii Code §480, *et seq.*, with respect to purchases of Suboxone Tablets in Hawaii by members of the Indirect Purchaser Class.
- f. Defendants have intentionally and wrongfully engaged in monopolization in the relevant market in violation of Iowa Code §§ 553, *et seq.*, with respect to purchases of Suboxone in Iowa by members of the Class.
- g. Defendants have intentionally and wrongfully engaged in monopolization in the relevant market in violation of Kan. Stat. Ann. §§ 50-101, *et seq.*, with respect to purchases of Suboxone in Kansas by members of the Class.
- h. Defendants have intentionally and wrongfully engaged in monopolization in the relevant market in violation of Me. Rev. Stat. Ann. 10, §§ 1102, *et seq.*, with respect to purchases of Suboxone in Maine by members of the Class.

- i. Defendants have intentionally and wrongfully engaged in monopolization in the relevant market in violation of Mass. Ann. Laws. Ch. 93A, *et seq.*, with respect to purchases of Suboxone in Massachusetts by members of the Class.
- j. Defendants have intentionally and wrongfully engaged in monopolization in the relevant market in violation of Mich. Comp. Laws Ann. §§ 445.772, *et seq.*, with respect to purchases of Suboxone in Michigan by members of the Class.
- k. Defendants have intentionally and wrongfully engaged in monopolization in the relevant market in violation of Minn. Stat. §§ 325D.52, *et seq.*, and Minn. Stat. § 8.31, *et seq.*, with respect to purchases of Suboxone in Minnesota by members of the Class.
- l. Defendants have intentionally and wrongfully engaged in monopolization in the relevant market in violation of Miss. Code Ann. §§ 75-21- 3, *et seq.*, with respect to purchases of Suboxone in Mississippi by members of the Class.
- m. Defendants have intentionally and wrongfully engaged in monopolization in the relevant market in violation of Mo. Rev. Stat. §§ 416.011, *et seq.*, with respect to purchases of Suboxone in Missouri by members of the Class.
- n. Defendants have intentionally and wrongfully engaged in monopolization in the relevant market in violation of Neb. Code Ann. §§ 59-802, *et seq.*, with respect to purchases of Suboxone in Nebraska by members of the Class.
- o. Defendants have intentionally and wrongfully engaged in monopolization in the relevant market in violation of Nev. Rev. Stat. Ann. §§ 598A.060, *et seq.*, with respect to purchases of Suboxone in Nevada by members of the Class.
- p. Defendants have intentionally and wrongfully engaged in monopolization in the relevant market in violation of N.H. Rev. State. Ann. §§ 356, 356:2, 356:3, *et seq.*, with respect to purchases of Suboxone in New Hampshire by members of the Class.
- q. Defendants have intentionally and wrongfully engaged in monopolization in the relevant market in violation of N.M. Stat. Ann. §§ 57-1-2, *et seq.*, with respect to purchases of Suboxone in New Mexico by members of the Class.

- r. Defendants have intentionally and wrongfully engaged in monopolization in the relevant market in violation of New York General Business Law §§ 340, *et seq.*, with respect to purchases of Suboxone in New York by members of the Class.
- s. Defendants have intentionally and wrongfully engaged in monopolization in the relevant market in violation of N.C. Gen. Stat. §§ 75-2.1, *et seq.*, with respect to purchases of Suboxone in North Carolina by members of the Class.
- t. Defendants have intentionally and wrongfully engaged in monopolization in the relevant market in violation of N.D. Cent. Code §§ 51- 08.1-02, *et seq.*, with respect to purchases of Suboxone in North Dakota by members of the Class.
- u. Defendants have intentionally and wrongfully engaged in monopolization in the relevant market in violation of Or. Rev. Stat. §§ 646.705, *et seq.*, with respect to purchases of Suboxone Tablets in Oregon by members of the Indirect Purchaser Class.
- v. Defendants have intentionally and wrongfully engaged in monopolization in the relevant market in violation of S.D. Codified Laws Ann. §§ 37-1-3.2, *et seq.*, with respect to purchases of Suboxone in South Dakota by members of the Class.
- w. Defendants have intentionally and wrongfully engaged in monopolization in the relevant market in violation of Tenn. Code Ann. §§ 47-25- 101, *et seq.*, with respect to purchases of Suboxone in Tennessee by members of the Class.
- x. Defendants have intentionally and wrongfully engaged in monopolization in the relevant market in violation of Utah Code Ann. §§ 76-10-911, *et seq.*, with respect to purchases of Suboxone in Utah by members of the Class.
- y. Defendants have intentionally and wrongfully engaged in monopolization in the relevant market in violation of Vt. Stat. Ann. 9, §§ 2453, *et seq.*, with respect to purchases of Suboxone in Vermont by members of the Class.
- z. Defendants have intentionally and wrongfully engaged in monopolization in the relevant markets in violation of W.Va. Code §§ 47-18-3, *et seq.*, with respect to purchases of Suboxone in West Virginia by members of the Class.

- aa. Defendants have intentionally and wrongfully engaged in monopolization in the relevant market in violation of Wis. Stat. §§ 133.03, *et seq.*, with respect to purchases of Suboxone in Wisconsin by members of the Class.

COUNT II

Monopolization: Unlawful Maintenance of Monopoly Power By Conversion Of The Market From Tablet To Film Formulation

148. Plaintiff refers to, and incorporates herein, the allegations above in ¶¶ 1-147.

149. During the relevant period, Reckitt willfully and unlawfully maintained its monopoly power by engaging in exclusionary conduct that discouraged rather than encouraged competition on the merits. As explained in detail above, Reckitt unlawfully converted the market from Suboxone Tablets to Suboxone Film, which is no safer or more effective than Suboxone Tablets by, *inter alia*, (a) raising the price of Suboxone Tablets in relation to Suboxone Film; (b) directing its detailers to market only Suboxone Film and to urge physicians not to write prescriptions for Suboxone Tablets; (c) intentionally refusing to unit-dose pack Suboxone Tablets for the purpose of creating the illusion that Suboxone Film is a superior product; and (d) stating its intent to withdraw Suboxone Tablets from the market.

150. The goal, purpose and/or effect of Reckitt's conduct was to prevent, delay, and/or minimize the success of the entry of generic competitors which would have sold generic Suboxone Tablets in the United States at prices significantly below Reckitt's prices for Suboxone, which would have effectively caused the average market price of Suboxone to decline dramatically.

151. The goal, purpose and/or effect of Reckitt's conduct was also to maintain and extend Reckitt's monopoly power with respect to BPN/NLX. Reckitt's illegal conduct, calculated and designed to exclude, delay, and/or minimize the success of the introduction into

the United States marketplace of any generic version of Suboxone, enabled Reckitt to continue charging supra-competitive prices for BPN/NLX without a substantial loss of sales.

152. As a result of Reckitt's illegal scheme, Plaintiff and members of the End-Payor Class more than they would have paid for BPN/NLX, absent Reckitt's illegal conduct. But for Reckitt's illegal conduct, competitors would have begun marketing generic versions of Suboxone well before they actually did, and/or would have been able to market such versions more successfully upon entry than they actually did.

153. If manufacturers of generic BPN/NLX had been able to enter the market and compete with Reckitt in a full and timely fashion, Plaintiff and members of the End-Payor Class would have substituted lower-priced generic BPN/NLX for some or all of their BPN/NLX requirements, and/or would have received lower prices on some or all of their remaining branded Suboxone purchases.

154. During the relevant period, Plaintiff and the members of the End-Payor Class purchased substantial amounts of Suboxone directly from Reckitt. As a result of Reckitt's illegal conduct alleged herein, Plaintiff and the other members of the End-Payor Class were compelled to pay, and did pay, artificially inflated prices for their BPN/NLX requirements. Plaintiff and members of the End-Payor Class paid prices for BPN/NLX that were substantially greater than the prices that they would have paid absent the illegal conduct alleged herein, because: (a) class members were deprived of the opportunity to purchase lower-priced generic BPN/NLX instead of expensive brand-name Suboxone; and/or (b) the price of branded Suboxone was artificially inflated by Reckitt's illegal conduct.

155. The injury to the Plaintiff and the members of the End-Payor Class is the type of injury state antitrust laws are designed to prevent, and the injury was a direct and proximate result of Defendant Reckitt's unlawful conduct.

156. Reckitt's intentional conversion of the market from the tablet to the film formulation was an act of monopolization undertaken with the specific intent to monopolize the market for BPN/NLX in the United States .

157. Plaintiff and the End-Payor Class seek damages and multiple damages as permitted by law for their injuries by Reckitt's violations of the following state antitrust laws:

- a. Defendants have intentionally and wrongfully engaged in monopolization in the relevant market in violation of Arizona Rev. Stat. §§ 44- 1402, *et seq.*, with respect to purchases of Suboxone in Arizona by members of the Class.
- b. Defendants have intentionally and wrongfully engaged in monopolization in the relevant market in violation of Cal. Bus. & Prof. Code §§ 16700, *et seq.*, with respect to purchases of Suboxone in California by members of the Class.
- c. Defendants have intentionally and wrongfully engaged in monopolization in the relevant market in violation of D.C. Code §§ 28-4503, *et seq.*, with respect to purchases of Suboxone in the District of Columbia by members of the Class.
- d. Defendants have intentionally and wrongfully engaged in monopolization in the relevant market in violation of Fla. Stat. §§ 501.201, *et seq.*, with respect to purchases of Suboxone in Florida by members of the Class.
- e. Defendants have intentionally and wrongfully engaged in monopolization in the relevant market in violation of Hawaii Code §480, *et seq.*, with respect to purchases of Suboxone Tablets in Hawaii by members of the Indirect Purchaser Class.
- f. Defendants have intentionally and wrongfully engaged in monopolization in the relevant market in violation of Iowa Code §§ 553, *et seq.*, with respect to purchases of Suboxone in Iowa by members of the Class.
- g. Defendants have intentionally and wrongfully engaged in monopolization in the relevant market in violation of Kan. Stat. Ann. §§ 50-101, *et seq.*,

with respect to purchases of Suboxone in Kansas by members of the Class.

- h. Defendants have intentionally and wrongfully engaged in monopolization in the relevant market in violation of Me. Rev. Stat. Ann. 10, §§ 1102, *et seq.*, with respect to purchases of Suboxone in Maine by members of the Class.
- i. Defendants have intentionally and wrongfully engaged in monopolization in the relevant market in violation of Mass. Ann. Laws. Ch. 93A, *et seq.*, with respect to purchases of Suboxone in Massachusetts by members of the Class.
- j. Defendants have intentionally and wrongfully engaged in monopolization in the relevant market in violation of Mich. Comp. Laws Ann. §§ 445.772, *et seq.*, with respect to purchases of Suboxone in Michigan by members of the Class.
- k. Defendants have intentionally and wrongfully engaged in monopolization in the relevant market in violation of Minn. Stat. §§ 325D.52, *et seq.*, and Minn. Stat. § 8.31, *et seq.*, with respect to purchases of Suboxone in Minnesota by members of the Class.
- l. Defendants have intentionally and wrongfully engaged in monopolization in the relevant market in violation of Miss. Code Ann. §§ 75-21- 3, *et seq.*, with respect to purchases of Suboxone in Mississippi by members of the Class.
- m. Defendants have intentionally and wrongfully engaged in monopolization in the relevant market in violation of Mo. Rev. Stat. §§ 416.011, *et seq.*, with respect to purchases of Suboxone in Missouri by members of the Class.
- n. Defendants have intentionally and wrongfully engaged in monopolization in the relevant market in violation of Neb. Code Ann. §§ 59-802, *et seq.*, with respect to purchases of Suboxone in Nebraska by members of the Class.
- o. Defendants have intentionally and wrongfully engaged in monopolization in the relevant market in violation of Nev. Rev. Stat. Ann. §§ 598A.060, *et seq.*, with respect to purchases of Suboxone in Nevada by members of the Class.

- p. Defendants have intentionally and wrongfully engaged in monopolization in the relevant market in violation of N.H. Rev. State. Ann. §§ 356, 356:2, 356:3, *et seq.*, with respect to purchases of Suboxone in New Hampshire by members of the Class.
- q. Defendants have intentionally and wrongfully engaged in monopolization in the relevant market in violation of N.M. Stat. Ann. §§ 57-1-2, *et seq.*, with respect to purchases of Suboxone in New Mexico by members of the Class.
- r. Defendants have intentionally and wrongfully engaged in monopolization in the relevant market in violation of New York General Business Law §§ 340, *et seq.*, with respect to purchases of Suboxone in New York by members of the Class.
- s. Defendants have intentionally and wrongfully engaged in monopolization in the relevant market in violation of N.C. Gen. Stat. §§ 75-2.1, *et seq.*, with respect to purchases of Suboxone in North Carolina by members of the Class.
- t. Defendants have intentionally and wrongfully engaged in monopolization in the relevant market in violation of N.D. Cent. Code §§ 51-08.1-02, *et seq.*, with respect to purchases of Suboxone in North Dakota by members of the Class.
- u. Defendants have intentionally and wrongfully engaged in monopolization in the relevant market in violation of Or. Rev. Stat. §§ 646.705, *et seq.*, with respect to purchases of Suboxone Tablets in Oregon by members of the Indirect Purchaser Class.
- v. Defendants have intentionally and wrongfully engaged in monopolization in the relevant market in violation of S.D. Codified Laws Ann. §§ 37-1-3.2, *et seq.*, with respect to purchases of Suboxone in South Dakota by members of the Class.
- w. Defendants have intentionally and wrongfully engaged in monopolization in the relevant market in violation of Tenn. Code Ann. §§ 47-25-101, *et seq.*, with respect to purchases of Suboxone in Tennessee by members of the Class.
- x. Defendants have intentionally and wrongfully engaged in monopolization in the relevant market in violation of Utah Code Ann. §§ 76-10-911, *et seq.*, with respect to purchases of Suboxone in Utah by members of the Class.

- y. Defendants have intentionally and wrongfully engaged in monopolization in the relevant market in violation of Vt. Stat. Ann. 9, §§ 2453, *et seq.*, with respect to purchases of Suboxone in Vermont by members of the Class.
- z. Defendants have intentionally and wrongfully engaged in monopolization in the relevant markets in violation of W.Va. Code §§ 47-18-3, *et seq.*, with respect to purchases of Suboxone in West Virginia by members of the Class.
- aa. Defendants have intentionally and wrongfully engaged in monopolization in the relevant market in violation of Wis. Stat. §§ 133.03, *et seq.*, with respect to purchases of Suboxone in Wisconsin by members of the Class.

COUNT III

Monopolization: Unlawful Maintenance Of Monopoly Power By Intentionally Delaying The SSRS Process And Violating 21 U.S.C. § 355-108)

158. Plaintiff refers to, and incorporates herein, the allegations above in ¶¶ 1-157.

159. During the relevant period, Reckitt willfully and unlawfully maintained its monopoly power by feigning cooperation with the sponsors of generic Suboxone Tablet ANDAs and intentionally delaying the creation of unified or generics-only REMS for Suboxone Tablets.

160. The goal, purpose and/or effect of Reckitt's conduct was to exclude, delay, and/or minimize the success of the entry of generic competitors which would have sold generic Suboxone Tablets in the United States at prices significantly below Reckitt's prices for branded Suboxone, which would have effectively caused the average market price of Suboxone to decline dramatically.

161. The goal, purpose and/or effect of Reckitt's conduct was also to maintain and extend Reckitt's monopoly power with respect to BPN/NLX. Reckitt's illegal conduct, calculated and designed to prevent, delay, and/or minimize the success of the introduction into the United States marketplace of any generic version of Suboxone, enabled Reckitt to continue charging supra-competitive prices for BPN/NLX without a substantial loss of sales.

162. As a result of Reckitt's illegal conduct, Plaintiff and members of the End-Payor Class paid more than they would have paid for BPN/NLX, absent that illegal conduct. But for Reckitt's illegal conduct, competitors would have begun marketing generic versions of Suboxone well before they actually will, and/or would have been able to market such versions more successfully upon entry than they actually will.

163. If manufacturers of generic BPN/NLX had been able to enter the market and compete with Reckitt in a full and timely fashion, Plaintiff and members of the End-Payor Class would have substituted lower-priced generic BPN/NLX for some or all of their BPN/NLX requirements, and/or would have received lower prices on some or all of their remaining branded Suboxone purchases.

164. As a result of Reckitt's illegal scheme, Plaintiff and members of the End-Payor Class more than they would have paid for BPN/NLX, absent Reckitt's illegal conduct. But for Reckitt's illegal conduct, competitors would have begun marketing generic versions of Suboxone well before they actually did, and/or would have been able to market such versions more successfully upon entry than they actually did.

165. If manufacturers of generic BPN/NLX had been able to enter the market and compete with Reckitt in a full and timely fashion, Plaintiff and members of the End-Payor Class would have substituted lower-priced generic BPN/NLX for some or all of their BPN/NLX requirements, and/or would have received lower prices on some or all of their remaining branded Suboxone purchases.

166. During the relevant period, Plaintiff and the members of the End-Payor Class purchased substantial amounts of Suboxone directly from Reckitt. As a result of Reckitt's illegal conduct alleged herein, Plaintiff and the other members of the End-Payor Class were compelled

to pay, and did pay, artificially inflated prices for their BPN/NLX requirements. Plaintiff and members of the End-Payor Class paid prices for BPN/NLX that were substantially greater than the prices that they would have paid absent the illegal conduct alleged herein, because: (a) class members were deprived of the opportunity to purchase lower-priced generic BPN/NLX instead of expensive brand-name Suboxone; and/or (b) the price of branded Suboxone was artificially inflated by Reckitt's illegal conduct.

167. The injury to the Plaintiff and the members of the End-Payor Class is the type of injury state antitrust laws are designed to prevent, and the injury was a direct and proximate result of Defendant Reckitt's unlawful conduct.

168. Reckitt's conduct in intentionally delaying the creation of an SSRS for Suboxone Tablets was an act of monopolization undertaken with the specific intent to monopolize the market for BPN/NLX in the United States.

169. Plaintiff and the End-Payor Class seek damages and multiple damages as permitted by law for their injuries by Reckitt's violations of the following state antitrust laws:

- a. Defendants have intentionally and wrongfully engaged in monopolization in the relevant market in violation of Arizona Rev. Stat. §§ 44- 1402, *et seq.*, with respect to purchases of Suboxone in Arizona by members of the Class.
- b. Defendants have intentionally and wrongfully engaged in monopolization in the relevant market in violation of Cal. Bus. & Prof. Code §§ 16700, *et seq.*, with respect to purchases of Suboxone in California by members of the Class.
- c. Defendants have intentionally and wrongfully engaged in monopolization in the relevant market in violation of D.C. Code §§ 28-4503, *et seq.*, with respect to purchases of Suboxone in the District of Columbia by members of the Class.

- d. Defendants have intentionally and wrongfully engaged in monopolization in the relevant market in violation of Fla. Stat. §§ 501.201, *et seq.*, with respect to purchases of Suboxone in Florida by members of the Class.
- e. Defendants have intentionally and wrongfully engaged in monopolization in the relevant market in violation of Hawaii Code §480, *et seq.*, with respect to purchases of Suboxone Tablets in Hawaii by members of the Indirect Purchaser Class.
- f. Defendants have intentionally and wrongfully engaged in monopolization in the relevant market in violation of Iowa Code §§ 553, *et seq.*, with respect to purchases of Suboxone in Iowa by members of the Class.
- g. Defendants have intentionally and wrongfully engaged in monopolization in the relevant market in violation of Kan. Stat. Ann. §§ 50-101, *et seq.*, with respect to purchases of Suboxone in Kansas by members of the Class.
- h. Defendants have intentionally and wrongfully engaged in monopolization in the relevant market in violation of Me. Rev. Stat. Ann. 10, §§ 1102, *et seq.*, with respect to purchases of Suboxone in Maine by members of the Class.
- i. Defendants have intentionally and wrongfully engaged in monopolization in the relevant market in violation of Mass. Ann. Laws. Ch. 93A, *et seq.*, with respect to purchases of Suboxone in Massachusetts by members of the Class.
- j. Defendants have intentionally and wrongfully engaged in monopolization in the relevant market in violation of Mich. Comp. Laws Ann. §§ 445.772, *et seq.*, with respect to purchases of Suboxone in Michigan by members of the Class.
- k. Defendants have intentionally and wrongfully engaged in monopolization in the relevant market in violation of Minn. Stat. §§ 325D.52, *et seq.*, and Minn. Stat. § 8.31, *et seq.*, with respect to purchases of Suboxone in Minnesota by members of the Class.
- l. Defendants have intentionally and wrongfully engaged in monopolization in the relevant market in violation of Miss. Code Ann. §§ 75-21- 3, *et seq.*, with respect to purchases of Suboxone in Mississippi by members of the Class.

- m. Defendants have intentionally and wrongfully engaged in monopolization in the relevant market in violation of Mo. Rev. Stat. §§ 416.011, *et seq.*, with respect to purchases of Suboxone in Missouri by members of the Class.
- n. Defendants have intentionally and wrongfully engaged in monopolization in the relevant market in violation of Neb. Code Ann. §§ 59-802, *et seq.*, with respect to purchases of Suboxone in Nebraska by members of the Class.
- o. Defendants have intentionally and wrongfully engaged in monopolization in the relevant market in violation of Nev. Rev. Stat. Ann. §§ 598A.060, *et seq.*, with respect to purchases of Suboxone in Nevada by members of the Class.
- p. Defendants have intentionally and wrongfully engaged in monopolization in the relevant market in violation of N.H. Rev. State. Ann. §§ 356, 356:2, 356:3, *et seq.*, with respect to purchases of Suboxone in New Hampshire by members of the Class.
- q. Defendants have intentionally and wrongfully engaged in monopolization in the relevant market in violation of N.M. Stat. Ann. §§ 57-1-2, *et seq.*, with respect to purchases of Suboxone in New Mexico by members of the Class.
- r. Defendants have intentionally and wrongfully engaged in monopolization in the relevant market in violation of New York General Business Law §§ 340, *et seq.*, with respect to purchases of Suboxone in New York by members of the Class.
- s. Defendants have intentionally and wrongfully engaged in monopolization in the relevant market in violation of N.C. Gen. Stat. §§ 75-2.1, *et seq.*, with respect to purchases of Suboxone in North Carolina by members of the Class.
- t. Defendants have intentionally and wrongfully engaged in monopolization in the relevant market in violation of N.D. Cent. Code §§ 51- 08.1-02, *et seq.*, with respect to purchases of Suboxone in North Dakota by members of the Class.
- u. Defendants have intentionally and wrongfully engaged in monopolization in the relevant market in violation of Or. Rev. Stat. §§ 646.705, *et seq.*, with respect to purchases of Suboxone Tablets in Oregon by members of the Indirect Purchaser Class.

- v. Defendants have intentionally and wrongfully engaged in monopolization in the relevant market in violation of S.D. Codified Laws Ann. §§ 37-1-3.2, *et seq.*, with respect to purchases of Suboxone in South Dakota by members of the Class.
- w. Defendants have intentionally and wrongfully engaged in monopolization in the relevant market in violation of Tenn. Code Ann. §§ 47-25- 101, *et seq.*, with respect to purchases of Suboxone in Tennessee by members of the Class.
- x. Defendants have intentionally and wrongfully engaged in monopolization in the relevant market in violation of Utah Code Ann. §§ 76-10-911, *et seq.*, with respect to purchases of Suboxone in Utah by members of the Class.
- y. Defendants have intentionally and wrongfully engaged in monopolization in the relevant market in violation of Vt. Stat. Ann. 9, §§ 2453, *et seq.*, with respect to purchases of Suboxone in Vermont by members of the Class.
- z. Defendants have intentionally and wrongfully engaged in monopolization in the relevant markets in violation of W.Va. Code §§ 47-18-3, *et seq.*, with respect to purchases of Suboxone in West Virginia by members of the Class.
- aa. Defendants have intentionally and wrongfully engaged in monopolization in the relevant market in violation of Wis. Stat. §§ 133.03, *et seq.*, with respect to purchases of Suboxone in Wisconsin by members of the Class.

COUNT IV

Monopolization: Unlawful Maintenance Of Monopoly Power By Filing A Sham Citizen Petition

170. Plaintiff refers to, and incorporates herein, the allegations above in ¶¶ 1-169.

171. During the relevant period, Reckitt willfully and unlawfully maintained its monopoly power by filing a sham citizen petition with FDA on the eve of generic ANDA approval.

172. The goal, purpose and/or effect of Reckitt's conduct was to exclude, delay, and/or minimize the success of the entry of generic competitors which would have sold generic

Suboxone Tablets in the United States at prices significantly below Reckitt's prices for Suboxone, which would have effectively caused the average market price of Suboxone to decline dramatically.

173. The goal, purpose and/or effect of Reckitt's conduct was also to maintain and extend Reckitt's monopoly power with respect to BPN/NLX. Reckitt's illegal conduct, calculated and designed to prevent, delay, and/or minimize the success of the introduction into the United States marketplace of any generic version of Suboxone, enabled Reckitt to continue charging supra-competitive prices for BPN/NLX without a substantial loss of sales.

174. As a result of Reckitt's illegal scheme, Plaintiff and members of the End-Payor Class more than they would have paid for BPN/NLX, absent Reckitt's illegal conduct. But for Reckitt's illegal conduct, competitors would have begun marketing generic versions of Suboxone well before they actually did, and/or would have been able to market such versions more successfully upon entry than they actually did.

175. If manufacturers of generic BPN/NLX had been able to enter the market and compete with Reckitt in a full and timely fashion, Plaintiff and members of the End-Payor Class would have substituted lower-priced generic BPN/NLX for some or all of their BPN/NLX requirements, and/or would have received lower prices on some or all of their remaining branded Suboxone purchases.

176. During the relevant period, Plaintiff and the members of the End-Payor Class purchased substantial amounts of Suboxone directly from Reckitt. As a result of Reckitt's illegal conduct alleged herein, Plaintiff and the other members of the End-Payor Class were compelled to pay, and did pay, artificially inflated prices for their BPN/NLX requirements. Plaintiff and members of the End-Payor Class paid prices for BPN/NLX that were substantially greater than

the prices that they would have paid absent the illegal conduct alleged herein, because: (a) class members were deprived of the opportunity to purchase lower-priced generic BPN/NLX instead of expensive brand-name Suboxone; and/or (b) the price of branded Suboxone was artificially inflated by Reckitt's illegal conduct.

177. The injury to the Plaintiff and the members of the End-Payor Class is the type of injury state antitrust laws are designed to prevent, and the injury was a direct and proximate result of Defendant Reckitt's unlawful conduct.

178. Reckitt's conduct in intentionally and fraudulently delaying the filing of the citizen petition until the eve of generic ANDA approval was an act of monopolization undertaken with the specific intent to monopolize the market for BPN/NLX in the United States.

179. Plaintiff and the End-Payor Class seek damages and multiple damages as permitted by law for their injuries by Reckitt's violations of the following state antitrust laws:

- a. Defendants have intentionally and wrongfully engaged in monopolization in the relevant market in violation of Arizona Rev. Stat. §§ 44- 1402, *et seq.*, with respect to purchases of Suboxone in Arizona by members of the Class.
- b. Defendants have intentionally and wrongfully engaged in monopolization in the relevant market in violation of Cal. Bus. & Prof. Code §§ 16700, *et seq.*, with respect to purchases of Suboxone in California by members of the Class.
- c. Defendants have intentionally and wrongfully engaged in monopolization in the relevant market in violation of D.C. Code §§ 28-4503, *et seq.*, with respect to purchases of Suboxone in the District of Columbia by members of the Class.
- d. Defendants have intentionally and wrongfully engaged in monopolization in the relevant market in violation of Fla. Stat. §§ 501.201, *et seq.*, with respect to purchases of Suboxone in Florida by members of the Class.

- e. Defendants have intentionally and wrongfully engaged in monopolization in the relevant market in violation of Hawaii Code §480, *et seq.*, with respect to purchases of Suboxone Tablets in Hawaii by members of the Indirect Purchaser Class.
- f. Defendants have intentionally and wrongfully engaged in monopolization in the relevant market in violation of Iowa Code §§ 553, *et seq.*, with respect to purchases of Suboxone in Iowa by members of the Class.
- g. Defendants have intentionally and wrongfully engaged in monopolization in the relevant market in violation of Kan. Stat. Ann. §§ 50-101, *et seq.*, with respect to purchases of Suboxone in Kansas by members of the Class.
- h. Defendants have intentionally and wrongfully engaged in monopolization in the relevant market in violation of Me. Rev. Stat. Ann. 10, §§ 1102, *et seq.*, with respect to purchases of Suboxone in Maine by members of the Class.
- i. Defendants have intentionally and wrongfully engaged in monopolization in the relevant market in violation of Mass. Ann. Laws. Ch. 93A, *et seq.*, with respect to purchases of Suboxone in Massachusetts by members of the Class.
- j. Defendants have intentionally and wrongfully engaged in monopolization in the relevant market in violation of Mich. Comp. Laws Ann. §§ 445.772, *et seq.*, with respect to purchases of Suboxone in Michigan by members of the Class.
- k. Defendants have intentionally and wrongfully engaged in monopolization in the relevant market in violation of Minn. Stat. §§ 325D.52, *et seq.*, and Minn. Stat. § 8.31, *et seq.*, with respect to purchases of Suboxone in Minnesota by members of the Class.
- l. Defendants have intentionally and wrongfully engaged in monopolization in the relevant market in violation of Miss. Code Ann. §§ 75-21- 3, *et seq.*, with respect to purchases of Suboxone in Mississippi by members of the Class.
- m. Defendants have intentionally and wrongfully engaged in monopolization in the relevant market in violation of Mo. Rev. Stat. §§ 416.011, *et seq.*, with respect to purchases of Suboxone in Missouri by members of the Class.
- n. Defendants have intentionally and wrongfully engaged in monopolization in the relevant market in violation of Neb. Code Ann. §§ 59-802, *et seq.*, with respect to purchases of Suboxone in Nebraska by members of the

Class.

- o. Defendants have intentionally and wrongfully engaged in monopolization in the relevant market in violation of Nev. Rev. Stat. Ann. §§ 598A.060, *et seq.*, with respect to purchases of Suboxone in Nevada by members of the Class.
- p. Defendants have intentionally and wrongfully engaged in monopolization in the relevant market in violation of N.H. Rev. State. Ann. §§ 356, 356:2, 356:3, *et seq.*, with respect to purchases of Suboxone in New Hampshire by members of the Class.
- q. Defendants have intentionally and wrongfully engaged in monopolization in the relevant market in violation of N.M. Stat. Ann. §§ 57-1-2, *et seq.*, with respect to purchases of Suboxone in New Mexico by members of the Class.
- r. Defendants have intentionally and wrongfully engaged in monopolization in the relevant market in violation of New York General Business Law §§ 340, *et seq.*, with respect to purchases of Suboxone in New York by members of the Class.
- s. Defendants have intentionally and wrongfully engaged in monopolization in the relevant market in violation of N.C. Gen. Stat. §§ 75-2.1, *et seq.*, with respect to purchases of Suboxone in North Carolina by members of the Class.
- t. Defendants have intentionally and wrongfully engaged in monopolization in the relevant market in violation of N.D. Cent. Code §§ 51- 08.1-02, *et seq.*, with respect to purchases of Suboxone in North Dakota by members of the Class.
- u. Defendants have intentionally and wrongfully engaged in monopolization in the relevant market in violation of Or. Rev. Stat. §§ 646.705, *et seq.*, with respect to purchases of Suboxone Tablets in Oregon by members of the Indirect Purchaser Class.
- v. Defendants have intentionally and wrongfully engaged in monopolization in the relevant market in violation of S.D. Codified Laws Ann. §§ 37-1-3.2, *et seq.*, with respect to purchases of Suboxone in South Dakota by members of the Class.

- w. Defendants have intentionally and wrongfully engaged in monopolization in the relevant market in violation of Tenn. Code Ann. §§ 47-25- 101, *et seq.*, with respect to purchases of Suboxone in Tennessee by members of the Class.
- x. Defendants have intentionally and wrongfully engaged in monopolization in the relevant market in violation of Utah Code Ann. §§ 76-10-911, *et seq.*, with respect to purchases of Suboxone in Utah by members of the Class.
- y. Defendants have intentionally and wrongfully engaged in monopolization in the relevant market in violation of Vt. Stat. Ann. 9, §§ 2453, *et seq.*, with respect to purchases of Suboxone in Vermont by members of the Class.
- z. Defendants have intentionally and wrongfully engaged in monopolization in the relevant markets in violation of W.Va. Code §§ 47-18-3, *et seq.*, with respect to purchases of Suboxone in West Virginia by members of the Class.
- aa. Defendants have intentionally and wrongfully engaged in monopolization in the relevant market in violation of Wis. Stat. §§ 133.03, *et seq.*, with respect to purchases of Suboxone in Wisconsin by members of the Class.

COUNT V

Monopolization: Unlawful Maintenance Of Monopoly Power By Fraudulently Delaying The Filing Of The Citizen Petition

180. Plaintiff refers to, and incorporates herein, the allegations above in ¶¶ 1-179.

181. During the relevant period, Reckitt willfully and unlawfully maintained its monopoly power by intentionally and fraudulently delaying the filing of the citizen petition until the eve of generic ANDA approval.

182. The goal, purpose and/or effect of Reckitt's conduct was to exclude, delay, and/or minimize the success of the entry of generic competitors which would have sold generic Suboxone Tablets in the United States at prices significantly below Reckitt's prices for Suboxone, which would have effectively caused the average market price of Suboxone to decline dramatically.

183. The goal, purpose and/or effect of Reckitt's conduct was also to maintain and extend Reckitt's monopoly power with respect to BPN/NLX. Reckitt's illegal conduct, calculated and designed to prevent, delay, and/or minimize the success of the introduction into the United States marketplace of any generic version of Suboxone, enabled Reckitt to continue charging supra-competitive prices for BPN/NLX without a substantial loss of sales.

184. As a result of Reckitt's illegal conduct, Plaintiff and members of the End-Payor Class paid more than they would have paid for BPN/NLX, absent that illegal conduct. But for Reckitt's illegal conduct, competitors would have begun marketing generic versions of Suboxone well before they actually will, and/or would have been able to market such versions more successfully upon entry than they actually will.

185. If manufacturers of generic BPN/NLX had been able to enter the market and compete with Reckitt in a full and timely fashion, Plaintiff and members of the End-Payor Class would have substituted lower-priced generic BPN/NLX or the higher-priced brand-name Suboxone for some or all of their BPN/NLX requirements, and/or would have received lower prices on some or all of their remaining Suboxone purchases.

186. During the relevant period, Plaintiff and the members of the End-Payor Class purchased substantial amounts of Suboxone directly from Reckitt. As a result of Reckitt's illegal conduct alleged herein, Plaintiff and the other members of the End-Payor Class were compelled to pay, and did pay, artificially inflated prices for their BPN/NLX requirements. Plaintiff and members of the End-Payor Class paid prices for BPN/NLX that were substantially greater than the prices that they would have paid absent the illegal conduct alleged herein, because: (a) class members were deprived of the opportunity to purchase lower-priced generic BPN/NLX instead

of expensive brand-name Suboxone; and/or (b) the price of branded Suboxone was artificially inflated by Reckitt's illegal conduct.

187. The injury to the Plaintiff and the members of the End-Payor Class is the type of injury state antitrust laws are designed to prevent, and the injury was a direct and proximate result of Defendant Reckitt's unlawful conduct.

188. Reckitt's conduct in intentionally and fraudulently delaying the filing of the citizen petition until the eve of generic ANDA approval was an act of monopolization undertaken with the specific intent to monopolize the market for BPN/NLX in the United States.

189. Plaintiff and the End-Payor Class seek damages and multiple damages as permitted by law for their injuries by Reckitt's violations of the following state antitrust laws:

- a. Defendants have intentionally and wrongfully engaged in monopolization in the relevant market in violation of Arizona Rev. Stat. §§ 44- 1402, *et seq.*, with respect to purchases of Suboxone in Arizona by members of the Class.
- b. Defendants have intentionally and wrongfully engaged in monopolization in the relevant market in violation of Cal. Bus. & Prof. Code §§ 16700, *et seq.*, with respect to purchases of Suboxone in California by members of the Class.
- c. Defendants have intentionally and wrongfully engaged in monopolization in the relevant market in violation of D.C. Code §§ 28-4503, *et seq.*, with respect to purchases of Suboxone in the District of Columbia by members of the Class.
- d. Defendants have intentionally and wrongfully engaged in monopolization in the relevant market in violation of Fla. Stat. §§ 501.201, *et seq.*, with respect to purchases of Suboxone in Florida by members of the Class.
- e. Defendants have intentionally and wrongfully engaged in monopolization in the relevant market in violation of Hawaii Code §480, *et seq.*, with respect to purchases of Suboxone Tablets in Hawaii by members of the Indirect Purchaser Class.

- f. Defendants have intentionally and wrongfully engaged in monopolization in the relevant market in violation of Iowa Code §§ 553, *et seq.*, with respect to purchases of Suboxone in Iowa by members of the Class.
- g. Defendants have intentionally and wrongfully engaged in monopolization in the relevant market in violation of Kan. Stat. Ann. §§ 50-101, *et seq.*, with respect to purchases of Suboxone in Kansas by members of the Class.
- h. Defendants have intentionally and wrongfully engaged in monopolization in the relevant market in violation of Me. Rev. Stat. Ann. 10, §§ 1102, *et seq.*, with respect to purchases of Suboxone in Maine by members of the Class.
- i. Defendants have intentionally and wrongfully engaged in monopolization in the relevant market in violation of Mass. Ann. Laws. Ch. 93A, *et seq.*, with respect to purchases of Suboxone in Massachusetts by members of the Class.
- j. Defendants have intentionally and wrongfully engaged in monopolization in the relevant market in violation of Mich. Comp. Laws Ann. §§ 445.772, *et seq.*, with respect to purchases of Suboxone in Michigan by members of the Class.
- k. Defendants have intentionally and wrongfully engaged in monopolization in the relevant market in violation of Minn. Stat. §§ 325D.52, *et seq.*, and Minn. Stat. § 8.31, *et seq.*, with respect to purchases of Suboxone in Minnesota by members of the Class.
- l. Defendants have intentionally and wrongfully engaged in monopolization in the relevant market in violation of Miss. Code Ann. §§ 75-21- 3, *et seq.*, with respect to purchases of Suboxone in Mississippi by members of the Class.
- m. Defendants have intentionally and wrongfully engaged in monopolization in the relevant market in violation of Mo. Rev. Stat. §§ 416.011, *et seq.*, with respect to purchases of Suboxone in Missouri by members of the Class.
- n. Defendants have intentionally and wrongfully engaged in monopolization in the relevant market in violation of Neb. Code Ann. §§ 59-802, *et seq.*, with respect to purchases of Suboxone in Nebraska by members of the Class.

- o. Defendants have intentionally and wrongfully engaged in monopolization in the relevant market in violation of Nev. Rev. Stat. Ann. §§ 598A.060, *et seq.*, with respect to purchases of Suboxone in Nevada by members of the Class.
- p. Defendants have intentionally and wrongfully engaged in monopolization in the relevant market in violation of N.H. Rev. State. Ann. §§ 356, 356:2, 356:3, *et seq.*, with respect to purchases of Suboxone in New Hampshire by members of the Class.
- q. Defendants have intentionally and wrongfully engaged in monopolization in the relevant market in violation of N.M. Stat. Ann. §§ 57-1-2, *et seq.*, with respect to purchases of Suboxone in New Mexico by members of the Class.
- r. Defendants have intentionally and wrongfully engaged in monopolization in the relevant market in violation of New York General Business Law §§ 340, *et seq.*, with respect to purchases of Suboxone in New York by members of the Class.
- s. Defendants have intentionally and wrongfully engaged in monopolization in the relevant market in violation of N.C. Gen. Stat. §§ 75-2.1, *et seq.*, with respect to purchases of Suboxone in North Carolina by members of the Class.
- t. Defendants have intentionally and wrongfully engaged in monopolization in the relevant market in violation of N.D. Cent. Code §§ 51- 08.1-02, *et seq.*, with respect to purchases of Suboxone in North Dakota by members of the Class.
- u. Defendants have intentionally and wrongfully engaged in monopolization in the relevant market in violation of Or. Rev. Stat. §§ 646.705, *et seq.*, with respect to purchases of Suboxone Tablets in Oregon by members of the Indirect Purchaser Class.
- v. Defendants have intentionally and wrongfully engaged in monopolization in the relevant market in violation of S.D. Codified Laws Ann. §§ 37-1-3.2, *et seq.*, with respect to purchases of Suboxone in South Dakota by members of the Class.
- w. Defendants have intentionally and wrongfully engaged in monopolization in the relevant market in violation of Tenn. Code Ann. §§ 47-25- 101, *et seq.*, with respect to purchases of Suboxone in Tennessee by members of the Class.

- x. Defendants have intentionally and wrongfully engaged in monopolization in the relevant market in violation of Utah Code Ann. §§ 76-10-911, *et seq.*, with respect to purchases of Suboxone in Utah by members of the Class.
- y. Defendants have intentionally and wrongfully engaged in monopolization in the relevant market in violation of Vt. Stat. Ann. 9, §§ 2453, *et seq.*, with respect to purchases of Suboxone in Vermont by members of the Class.
- z. Defendants have intentionally and wrongfully engaged in monopolization in the relevant markets in violation of W.Va. Code §§ 47-18-3, *et seq.*, with respect to purchases of Suboxone in West Virginia by members of the Class.
- aa. Defendants have intentionally and wrongfully engaged in monopolization in the relevant market in violation of Wis. Stat. §§ 133.03, *et seq.*, with respect to purchases of Suboxone in Wisconsin by members of the Class.

COUNT VI

Unfair And Deceptive Trade Practices Under State Law

190. Plaintiff incorporates by reference the preceding paragraphs 1 through 189.

191. Defendants engaged in unfair competition or unfair, unconscionable, deceptive or fraudulent acts or practices in violation of the state consumer protection statutes listed below. As a direct and proximate result of Defendants' anticompetitive, deceptive, unfair, unconscionable, and fraudulent conduct, Plaintiff and members of the End-Payor Class are deprived of the opportunity to purchase a generic version of Suboxone and forced to pay higher prices for brand name Suboxone.

192. There is a gross disparity between the price that Plaintiff and the Class members pay for the brand product and the value received, given that a much cheaper substitute generic product should be available.

193. By engaging in the foregoing conduct, Defendants have violated the following state unfair and deceptive trade practices and consumer fraud laws:

- a. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Ark. Code § 4-88-101, *et seq.*, with respect to purchases of Suboxone in Arkansas by members of the Class.
- b. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Ariz.. Code § 44-1522, *et seq.*, with respect to purchases of Suboxone in Arizona by members of the Class.
- c. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Cal. Bus. & Prof. Code §§ 17200, *et seq.*, with respect to purchases of Suboxone in California by members of the Class.
- d. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of D.C. Code § 28-3901, *et seq.*, with respect to purchases of Suboxone in the District of Columbia by members of the Class.
- e. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Fla. Stat. § 501.201, *et seq.*, with respect to purchases of Suboxone in Florida by members of the Class.
- f. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Idaho Code § 48-601, *et seq.*, with respect to purchases of Suboxone in Idaho by members of the Class.
- g. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of 815 ILCS § 505/1, *et seq.*, with respect to purchases of Suboxone in Illinois by members of the Class.
- h. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of 5 Me. Rev. Stat. § 207, *et seq.*, with respect to purchases of Suboxone in Maine by members of the Class.
- i. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Mass. Gen. L. Ch. 93A, *et seq.*, with respect to purchases of Suboxone in Massachusetts by members of the Class.
- j. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Mich. Stat. § 445.901, *et seq.*, with respect to purchases of Suboxone in Michigan by members of the Class.
- k. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Minn. Stat. § 325F.68, *et seq.*, and Minn. Stat. § 8.31, *et seq.*, with respect to purchases of Suboxone in Minnesota by members of the Class.

- l. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Missouri Stat. § 407.010, *et seq.*, with respect to purchases of Suboxone in Missouri by members of the Class.
- m. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Neb. Rev. Stat. § 59-1601, *et seq.*, with respect to purchases of Suboxone in Nebraska by members of the Class.
- n. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Nev. Rev. Stat. § 598.0903, *et seq.*, with respect to purchases of Suboxone in Nevada by members of the Class.
- o. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of N.H. Rev. Stat. § 358-A: 1, *et seq.*, with respect to purchases of Suboxone in New Hampshire by members of the Class.
- p. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of N.M. Stat. § 57-12-1, *et seq.*, with respect to purchases of Suboxone in New Mexico by members of the Class.
- q. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of N.Y. Gen. Bus. Law § 349, *et seq.*, with respect to purchases of Suboxone in New York by members of the Class.
- r. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of N.C. Gen. Stat. § 75-1.2, *et seq.*, with respect to purchases of Suboxone in North Carolina by members of the Class.
- s. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Or. Rev. Stat. § 646.605, *et seq.*, with respect to purchases of Suboxone in Oregon by members of the Class.
- t. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of 73 Pa. Stat. Ann. §§ 201-1, *et seq.*, with respect to purchases of Suboxone in Pennsylvania by members of the Class.
- u. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of R.I. Gen. Laws §§ 6-13.1-1, *et seq.*, with respect to purchases of Suboxone in Rhode Island by members of the Class.
- v. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of S.D. Code Laws § 37-24-1, *et seq.*, with respect to purchases of Suboxone in South Dakota by members of the Class.
- w. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Tenn. Code § 47-18-101, *et seq.*, with respect to purchases of Suboxone in Tennessee by members of the Class.

- x. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Utah Code § 13-11-1, *et seq.*, with respect to purchases of Suboxone in Utah by members of the Class.
- y. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Vt. Stat. Ann. 9, § 2453, *et seq.*, with respect to purchases of Suboxone in Vermont by members of the Class.
- z. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Va. Code Ann. § 59.1-1 96, *et seq.*, with respect to purchases of Suboxone in Virginia by members of the Class.
- aa. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of West Virginia Code § 46A-6-101, *et seq.*, with respect to purchases of Suboxone in West Virginia by members of the Class.

194. Plaintiff and members of the Class have been injured in their business and property by reason of Defendants' anticompetitive, unfair or deceptive acts alleged in this Claim. Their injury consists of paying higher prices for Suboxone than they would have paid in the absence of these violations, and being denied the opportunity to purchase cheaper generic Suboxone. These injuries are of the type the state consumer protection and unfair business practices statutes were designed to prevent and directly result from Defendants' unlawful conduct.

COUNT VII

Declaratory And Injunctive Relief Under Section 16 Of The Clayton Act For Defendant's Violations Of Sections 1 And 2 Of The Sherman Act

195. Plaintiff incorporates by reference the preceding paragraphs 1 through 194.

196. Plaintiff's allegations described herein and in Claims I through VII comprise violations of Sections 1 and 2 of the Sherman Act, as well as the state laws *supra*.

197. Plaintiff and the Class, pursuant to Fed. R. Civ. P. 57 and 28 U.S.C. § 2201(a), hereby seek a declaratory judgment that Defendants' conduct in seeking to prevent competition as described herein violates Sections 1 and 2 of the Sherman Act.

198. Plaintiff and the Class further seek equitable and injunctive relief pursuant to Section 16 of the Clayton Act, 15 U.S.C. § 26, and other applicable law, to correct for the anticompetitive market effects caused by the unlawful conduct of Defendants, and other relief so as to assure that similar anticompetitive conduct does not reoccur in the future.

COUNT VIII

Unjust Enrichment (Fifty States & District Of Columbia, Except Ohio And Indiana)

199. Plaintiff incorporates by reference the preceding paragraphs 1 through 198.

200. Reckitt has benefited from the monopoly profits on the sale of Suboxone resulting from the unlawful and inequitable acts alleged in this Complaint.

201. Reckitt's financial benefit resulting from its unlawful and inequitable conduct is traceable to overpayments for Suboxone by Plaintiff and members of the End-Payor Class.

202. Plaintiff and the Class have conferred upon Defendants an economic benefit, in the nature of profits resulting from unlawful overcharges and monopoly profits, to the economic detriment of Plaintiff and the Class.

203. It would be futile for Plaintiff and the Class to seek a remedy from any party with whom they had privity of contract.

204. It would be futile for Plaintiff and the Class to seek to exhaust any remedy against the immediate intermediary in the chain of distribution from which it indirectly purchased Suboxone, as they are not liable and would not compensate Plaintiff for unlawful conduct caused by Reckitt.

205. The economic benefit of overcharges and unlawful monopoly profits derived by Reckitt through charging supracompetitive and artificially inflated prices for Suboxone is a direct and proximate result of Defendants' unlawful practices.

206. The financial benefits derived by Reckitt rightfully belong to Plaintiff and the Class, as Plaintiff and the Class paid anticompetitive and monopolistic prices during the Class Period, inuring to the benefit of Reckitt.

207. It would be inequitable under unjust enrichment principles in the District of Columbia and each of the fifty states, except for Ohio and Indiana, for Reckitt to be permitted to retain any of the overcharges for Suboxone derived from Reckitt's unfair and unconscionable methods, acts, and trade practices alleged in this complaint.

208. Reckitt was and continues to be aware of and appreciates the benefits bestowed upon it by Plaintiff and the members of the End-Payor Class.

209. Reckitt should be compelled to disgorge in a common fund for the benefit of Plaintiff and the Class all unlawful or inequitable proceeds it received.

210. A constructive trust should be imposed upon all unlawful or inequitable sums received by Reckitt traceable to Plaintiff and the Class.

211. Plaintiff and the Class have no adequate remedy at law.

Claims for Relief

WHEREFORE, Plaintiff, on behalf of itself and the Class, respectfully prays that:

A. The Court determine that this action may be maintained as a class action pursuant to Rule 23(a), (b)(2) and (b)(3) of the Federal Rules of Civil Procedure, and direct that reasonable notice of this action, as provided by Rule 23(c)(2) of the Federal Rules of Procedure, be given to the Class, and declare the Plaintiff as the representative of the Indirect Purchaser Class;

B. The acts alleged herein be adjudged and decreed to be in violation of state antitrust, consumer protection, and unjust enrichment laws as alleged herein;

C. Enter joint and several judgments against Defendants and in favor of Plaintiff and the Indirect Purchaser Class.

D. Permanently enjoin the Defendants pursuant to sections 4 and 16 of the Clayton Act, 15 U.S.C. §§15(a) and 26, from continuing their unlawful contact, so as to assure that similar anticompetitive conduct does not continue to occur in the future;

E. Award the Indirect Purchaser Class damages (*i.e.*, three times overcharges) in an amount to be determined at trial;

F. Award Plaintiff and the Indirect Purchaser Class equitable relief in the nature of disgorgement, restitution, and the creation of a construction trust to remedy Defendants' unjust enrichment;

G. Award Plaintiff and the Indirect Purchaser Class damages as permitted by law, including disgorgement;

H. Award Plaintiff and the Indirect Purchaser Class their costs of suit, including reasonable attorneys' fees as provided by law; and

I. Such other and further relief as the Court may deem just and proper.

JURY DEMAND

Plaintiff demands trial by jury of all issues so triable.

Dated: Burlington, Vermont
March 11, 2013



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